

FORMULARIO ÚNICO DE OPOSICIÓN

①

OPOSICIÓN A:

- | | |
|--|--|
| ☒ Patente de Invención. | ☐ Marca Colectiva. |
| ☒ Patente de Modelo de Utilidad. | ☐ Marca de Certificación. |
| ☒ Diseño Industrial. | ☐ Lema Comercial. |
| ☐ Esquema de Trazado para Circuitos Integrados. | |
| ☐ Marcas de Productos o Servicios. | |

②

Número del expediente: 08 011.002

Solicitante: **WORLD-TRADE IMPORT-EXPORT WTIE, A.G**

**SOLICITUD
PUBLICADA**

Apoderado: **DILIA MARIA RODRIGUEZ**

Título de la nueva creación o denominación del signo: COMPOSICIONES DE ISOFLAVONAS PARA EL TRATAMIENTO DE LOS SINTOMAS Y TRANSTORNOS FISIOLÓGICOS DE LA MENOPAUSIA

Gaceta: 605

③ OPOSICIÓN PRESENTADA POR:

SOLICITANTE	Nombre: PROCAPS S.A. Dirección: CALLE 80 No. 78b-201 Nacionalidad o Domicilio: COLOMBIA Lugar de Constitución: BARRANQUILLA	IDENTIFICACIÓN C.C. ☐ NIT ☒ C.E. ☐ Otro ☐ Cual _____ Número 890.106.527-5
	Teléfono: 371 99 00 Fax: 373 08 18 E-mail: _____	
REPRESENTANTE O APODERADO	Nombre: CIELO ANGELA PEÑA RODRIGUEZ Dirección: CARRERA 13 No. 119-95 Teléfono: (571)213 12 13 Fax: (571)612 19 79 E-mail: negocios@optimum-co.com	IDENTIFICACIÓN C.C. ☒ NIT ☐ C.E. ☐ Otro ☐ Cual _____ Número 51.940.252 TP 82701

④ FUNDAMENTOS DE LA OPOSICIÓN:

Art.14, 16, 18, 20 y 30 de la Decisión 486 de la CAN

Causal: No cumple con los requisitos de patentabilidad.

Signo opositor:

Justificación:

La presente solicitud no cumple con los requisitos de patentabilidad dado que lo revelado, ya se encontraba en el estado de la técnica o es posible derivarlo de la misma tal y como se demostrará en el capítulo “Fundamento de Hechos”.

⑤ Comprobante de pago No. _____

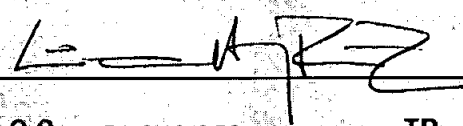
Fecha _____

⑥ ANEXOS

- ☒ Comprobante de pago de la tasa.
- ☒ Poderes, si fuere el caso.
- ☒ Pruebas de los fundamentos de la oposición.
- ☐ Documentos que acrediten el legítimo interés, si fuere el caso.
- ☒ Documento que acredita la existencia y representación legal de las partes, cuando sean personas jurídicas.

⑦

NOMBRE: CIELO ANGELA PEÑA RODRIGUEZ

FIRMA: 

C.C. 51.940.252

TP. 82701

Señora Jefe,

DIVISIÓN DE NUEVAS CREACIONES

Superintendencia de Industria y Comercio

E. S. D.

Referencia : Expediente N° 08 011.002 ✓
Asunto : Oposición a la solicitud de patente de Invención titulada
"COMPOSICION DE ISOFLAVONAS PARA
TRATAMIENTO DE LOS SINTOMAS Y TRASTORNOS
FISIOLOGICOS DE LA MENOPAUSIA"
Solicitante : WORLD-TRADE IMPORT-EXPORT WTIE
Opositora : PROCAPS S.A. ✓

Publicada en la Gaceta de la Propiedad Industrial
N° 605 del 30 de junio de 2009 ✓

Yo, *CIELO ANGELA PEÑA RODRIGUEZ*, abogada en ejercicio, identificada como aparece al pie de su firma, con tarjeta profesional No. *82701* del Consejo Superior de la Judicatura, en mi condición de apoderada de la sociedad *PROCAPS S.A.* conformada bajo las leyes de la República de Colombia y domiciliada en la ciudad de Barranquilla, Colombia, atentamente manifiesto que estando dentro del término de ley y por orden expresa de mi representada, presento oposición a la concesión del registro de la Patente de Invención titulada "COMPOSICION DE ISOFLAVONAS PARA TRATAMIENTO DE LOS SINTOMAS Y TRASTORNOS FISIOLOGICOS DE LA MENOPAUSIA", cuyo titular es WORLD-TRADE IMPORT-EXPORT WTIE., y

pido a Usted declarar fundada esta oposición y en consecuencia negar el registro de la patente solicitada.

1. INTERÉS PARA ACTUAR ✓

Conforme a lo dispuesto en el artículo 42 de la Decisión 486 de 2000 de la CAN, estando dentro del término estipulado por la ley, manifiesto el legítimo interés de nuestra representada para oponerse al registro de la patente de la referencia, atendiendo a que la solicitud pretendida no cumple con los requisitos dispuestos en la ley como se analizará más adelante y de ser concedida afectaría directamente la comercialización de algunos productos de mi representada, que contienen, en particular COMPOSICIONES DE ISOFLAVONAS. Por lo tanto, solicito respetuosamente a ese Despacho se sirva tener en cuenta la presente oposición dentro del trámite administrativo que se surte en esta Superintendencia.

2. FUNDAMENTOS DE HECHOS

- 2.1. La solicitud objeto de la presente fue presentada el 5 de febrero de 2008 reivindicando prioridad bajo la solicitud MX2005PA08573 del 2005-08-12; y fue publicada en Colombia, en la Gaceta de la Propiedad Industrial N° 605 del 30 de junio de 2009, cuya publicación internacional corresponde a la WO2007021166 del 2007-02-22.
- 2.2. La solicitud colombiana 08 011.002 objeto de la presente oposición, se refiere a compuestos fitoquímicos en general con propiedades biológicas que tienen efectos sobre una diversidad de procesos bioquímicos y fisiológicos del organismo

humano, en particular está referida a los fitoestrógenos con propiedades potenciales benéficas para la salud y específicamente está referida con una composición de isoflavonas para el tratamiento de los síntomas de menopausia: caracterizada la composición por comprender isoflavonas de Glycine max; al menos una o una mezcla de vitaminas de la composición, se seleccionan del grupo que consiste de vitamina A, niacina, vitamina B, vitamina C, vitamina D, vitamina E, ácido fólico y/o vitamina K, ácido pantoténico y al menos uno o una mezcla de minerales se seleccionan del grupo que consiste de cromo, magnesio, manganeso, calcio, cobre, zinc, hierro, potasio, fósforo o cualquier otro de consumo humano.

2.3. Ahora bien, con base en el artículo 14 de la Decisión 486 de la CAN consagra lo siguiente: *"Los países miembros otorgarán patentes para las invenciones, sean de producto o procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*. Así las cosas, las invenciones objeto de patente deben ser nuevas y tener nivel inventivo. Bien, pues antes de la fecha de prioridad de esta solicitud se encuentran los siguientes documentos que afecta la patentabilidad de la presente solicitud:

- D1: US6150399 publicada el 21 de noviembre de 2000.
- D2: US6096343 publicada el 1 de agosto de 2000.

2.4. Ahora bien, el documento D1, se relaciona generalmente con un completo alimenticio que proporciona la proteína de soja y los niveles realzados de isoflavones. Preferentemente según D1, la proteína de soja comprende al menos 0.7 mg de isoflavones y al menos 0.5 mg de genisteína, donde el producto es fortificado en el 35 % de RDI para el calcio y contiene un paquete de antioxidante. Particularmente en la columna 6, líneas 11 y 12, ejemplo 1, tabla 3, y reivindicaciones 1, 2 y 15, se refiere a productos basados en soja enriquecidos con

calcio al que se le puede añadir sales de potasio, magnesio y vitaminas como la A, Vitaminas del complejo B, Vitaminas C, O, E, K, Niacina, Ácido Fólico, Ácido Pantoténico (reivindicación 15), anticipando con ello las reivindicación en estudio. Así las cosas, como lo evidencia dicho documento D1, la presente solicitud no es novedosa pues lo revelado ya se encontraba en el estado de la técnica

2.5. Por su parte, el documento D2, divulga gránulos de isoflavonas con compuestos de calcio (columna 1, líneas 20 30) al que se añaden vitaminas A, O, C, E, ácido fólico, pantotenato de calcio y elementos como manganeso, cobre, zinc y minerales como potasio, magnesio, hierro (columna 2, línea 66 - columna 3, línea 10; columna 4, Ejemplo 4), anticipando también las características técnicas de la invención reivindicada. Por lo tanto, este documento objeto de oposición a la luz del documento D2 carece evidentemente de NOVEDAD, dado que dicha materia ya era conocida a la fecha de prioridad de la presente.

2.6. En consecuencia y de acuerdo a lo descrito anteriormente, se deriva que la solicitud colombiana 08 011.002 no puede pretender un monopolio por patente toda vez que lo que pretende no cumple con uno de los tres requisitos necesarios para su protección.

2.7. Que por consiguiente, respecto a la solicitud pretendida se tiene que:

2.7.1. **CARECE DE NOVEDAD:** Según la decisión 486 de la Comunidad Andina de Naciones, Artículo 16.- *“Una invención se considerará nueva cuando no está comprendida en el estado de la técnica. El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida.”*. A la fecha de prioridad, 12 de agosto de 2005 ya era conocido, pues como se demostró, era parte del arte anterior con base en el documento D1 y D2, compuestos fitoquímicos en general con propiedades biológicas que tienen efectos sobre una diversidad de

procesos bioquímicos y fisiológicos del organismo humano, en particular está referida a los fitoestrógenos con propiedades potenciales benéficas para la salud y específicamente está referida con una composición de isoflavonas para el tratamiento de los síntomas de menopausia, sobre el cual busca protección en el capítulo reivindicatorio.

2.8. Dado lo anterior, es posible deducir que la solicitud y lo reivindicado no es objeto de patentabilidad pues es contrario a lo que dicta la Decisión 486 de la Comunidad Andina de Naciones, Artículo 14.- *“Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial.”*. La solicitud pretendida no cumple con dos de los tres requisitos de patentabilidad.

2.9. Por todo lo anterior, atentamente solicito a usted que se sirva declarar fundada la presente oposición y negar el registro Patente de invención denominada **“COMPOSICION DE ISOFLAVONAS PARA TRATAMIENTO DE LOS SINTOMAS Y TRASTORNOS FISIOLÓGICOS DE LA MENOPAUSIA”**, cuyo titular es **WORLD-TRADE IMPORT-EXPORT WTIE**, solicitud Colombiana que apareció publicada en la Gaceta de la Propiedad Industrial N° 605 del 30 de junio de 2009.

3. PRUEBAS

De conformidad con lo dispuesto por las normas vigentes, solicito a usted tener como prueba en este asunto los siguientes:

- D1: US6150399 publicada el 21 de noviembre de 2000.
- D2: US6096343 publicada el 1 de agosto de 2000.

4. FUNDAMENTO DE DERECHO

Fundamento esta observación en las normas legales siguientes:

- 4.1. Numeral 1 del artículo 586 del Código de Comercio.
- 4.2. Artículo 42 de la Decisión 486 de la Comisión del Acuerdo de Cartagena.
- 4.3. En las demás normas concordantes.

5. ANEXOS

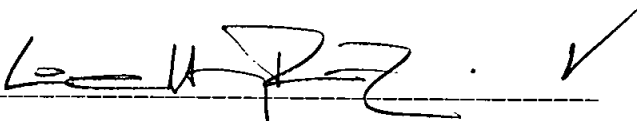
Para los efectos correspondientes anexo al presente escrito los siguientes documentos:

1. Poder para actuar en el presente.
2. Documento que acredita al representante legal de **PROCAPS S.A.**
3. Recibo de caja del respectivo pago de tasa.
4. Copias de los documentos:
 - D1: US6150399 publicada el 21 de noviembre de 2000.
 - D2: US6096343 publicada el 1 de agosto de 2000.

6. NOTIFICACIONES

Para efectos de notificaciones que por disposición del artículo 50 del Decreto 01 de 1984 debe hacer su Despacho, informo que mi representada y la suscrita recibiremos notificaciones en la Secretaría de su Despacho o en mis oficinas situadas en la Carrera 13 N° 119-95, Of. 104 de esta ciudad de Bogotá.

Señor Superintendente,



CIELO ANGELA PEÑA RODRIGUEZ

C.C. 51'940.252 de Bogotá

T.P.A. 82701 del C.S. de la J.



PODER ESPECIAL

Yo, **WALTER TANAKA TATEKAWA**, mayor de edad y vecino de la ciudad de Barranquilla (Colombia), identificado como aparece al pie de mi firma, quien en el presente documento actúa en calidad de Representante Legal de la sociedad **PROCAPS S.A.** sociedad legalmente constituida y domiciliada en la ciudad de Barranquilla (Colombia), por el presente documento otorgo a la doctora **CIELO ANGELA PEÑA RODRIGUEZ**, abogada en ejercicio, identificada como aparece al pie de su firma, con tarjeta profesional No. 82701 del C.S. de la J., poder especial, amplio y suficiente, para formular oposiciones u observaciones a la solicitud de patente No. 08 011.002, titulada "**COMPOSICION DE ISOFLAVONAS PARA TRATAMIENTO DE LOS SINTOMAS Y TRASTORNOS FISIOLÓGICOS DE LA MENOPAUSIA**", cuyo titular es **WORLD-TRADE IMPORT-EXPORT WTIE, A.G.**, publicada en la gaceta No. 605 del 30 de junio de 2009.

Nuestro apoderado queda facultado, de manera expresa, para realizar todo tipo de actos necesarios para llevar a cabo el trámite de la oposición, incluyendo, sin limitación, preparar y presentar solicitudes, hacer declaraciones, pagar tasas, contribuciones e impuestos, recabar los títulos o certificados. Asimismo quedan autorizados para impugnar administrativa y judicialmente todo lo que fuere resuelto en el expediente a que se hace expresa referencia en el presente poder, con todas las facultades generales y específicas que fuera requerido para ella.

De la misma manera, además de las facultades que le confiere la naturaleza del presente mandato, se encuentran facultados para recibir, desistir, transigir, sustituir, y reasumir el presente poder, incoar acciones, interponer recursos y demás facultades conferidas por la ley.

Dado y Firmado en Barranquilla (Colombia) a los 16 días del mes de Septiembre de 2009.

PROCAPS S.A.

C.C. N° 16'251.923

NIT: 890.106.527-5

Representante Legal

Acepto:

CIELO ANGELA PEÑA RODRIGUEZ

C.C. 51'940.252 de Bogotá

T.P.A. 82701 del C.S. de la J.

NOTARIA TERCERA DEL CIRCULO DE BARRANQUILLA
ALFONSO LUIS AVILA FADUL
DILIGENCIA DE PRESENTACIÓN PERSONAL Y
RECONOCIMIENTO

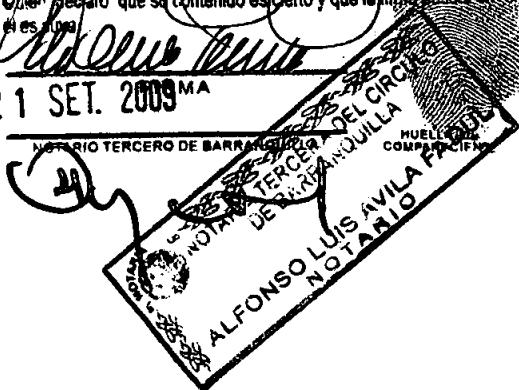
El suscrito Notario certifica que este escrito fue presentado personalmente por:

WALTER TANAKA TATEKAWA

Identificado con: 16.251.903 de VALBUENA

Quien declaró que su contenido es cierto y que la firma puesta en él es suya.

21 SET. 2009 MA





***** Pag. 1
CAMARA DE COMERCIO
DE BARRANQUILLA
08*****

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

PROCAPS S.A.-----

NIT: 890.106.527-5-----

EL SUSCRITO SECRETARIO DE LA CAMARA DE COMERCIO DE BARRANQUILLA, CON FUNDAMENTO EN LAS INSCRIPCIONES DEL REGISTRO MERCANTIL:

C E R T I F I C A

Que por Escritura Pública No. 1,190 del 22 de Julio de 1976, otorgada en la Notaria Tercera de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 28 de Julio de 1976 bajo el No. 6,070 del libro respectivo, fue constituida la sociedad----- limitada denominada "PRODUCTORA DE CAPSULAS DE GELATINAS LIMITADA "PROCAPS LIMITADA"-----

C E R T I F I C A

Que por Escritura Pública No. 1,307 del 28 de Junio de 1979, otorgada en la Notaria Tercera de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 23 de Julio de 1979 bajo el No. 10,039 del libro respectivo, la sociedad antes mencionada----- se transformo en sociedad anonima bajo la denominacion social de "PRODUCTORA DE CAPSULAS DE GELATINA S.A." "PROCAPS S.A."-----

C E R T I F I C A

Que por Escritura Pública No. 3,810 del 31 de Dic/bre de 1980, otorgada en la Notaria Primera de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 30 de Enero de 1981 bajo el No. 12,705 del libro respectivo, la sociedad antes mencionada----- se transformo en sociedad de responsabilidad limitada bajo al razon social de "PRODUCTORA DE CAPSULAS DE GELATINA LIMITADA "PROCAPS LI MITADA"-----

C E R T I F I C A

Que por Escritura Pública No. 3,755 del 10 de Nov/bre de 1983, otorgada en la Notaria Unica de Soledad, inscrito(as) en esta Cámara de Comercio, el 22 de Nov/bre de 1983 bajo el No. 17,922 del libro respectivo, la sociedad antes mencionada----- se transformo en sociedad anonima bajo la denominacion social de "PRODUCTORA DE CAPSULAS DE GELATINA S.A." "PROCAPS S.A."-----

C E R T I F I C A

Que por Escritura Pública No. 3,615 del 06 de Dic/bre de 1996, otorgada en la Notaria 2a. de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 20 de Dic/bre de 1996 bajo el No. 67,218 del

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

PROCAPS S.A.

NIT: 890.106.527-5.

Libro respectivo, la sociedad antes mencionada cambio de razon social, por la denominacion LABORATORIOS PROCAPS S.A.

C E R T I F I C A

Que por Escritura Pública No. 3,775 del 18 de Dic/bre de 1996 otorgada en la Notaria 2a de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 23 de Enero de 1997 bajo el No. 67,704 del libro respectivo, la sociedad antes mencionada cambio de razon social, por la denominacion PROCAPS S.A.

C E R T I F I C A

Que dicha sociedad ha sido reformada por las siguientes escrituras y/o documentos privados:

Numero	aaaa/mm/dd	Notaria	No	Insc o Reg	aaaa/mm/dd
39	1979/01/18	Notaria 3a. de Barranquilla.	9,452		1979/01/24
992	1981/04/30	Notaria 1a. de Barranquilla.	13,112		1981/05/06
1,464	1982/08/27	Notaria Unica de Soledad	15,533		1982/09/08
2,744	1983/08/18	Notaria Unica de Soledad	17,416		1983/08/26
3,826	1984/07/16	Notaria Unica de Soledad	19,554		1984/07/27
3,835	1985/08/26	Notaria Unica de Soledad	22,230		1985/09/04
2,260	1986/09/10	Notaria Unica de Soledad	24,995		1986/09/15
1,849	1989/07/11	Notaria 2a. de Barranquilla.	33,909		1989/07/13
444	1990/02/21	Notaria 2a. de Barranquilla.	36,101		1990/03/16
3,090	1991/12/17	Notaria 2a. de Barranquilla.	43,993		1992/01/28
269	1993/02/01	Notaria 2a. de Barranquilla.	48,428		1993/02/16
2,342	1993/07/28	Notaria 2a. de Barranquilla.	50,582		1993/08/10
3,652	1993/11/09	Notaria 2a. de Barranquilla.	51,798		1993/11/22
3,615	1996/12/06	Notaria 2a. de Barranquilla.	67,218		1996/12/20
89	1997/01/16	Notaria 2a. de Barranquilla.	67,704		1997/01/23
2,070	1997/07/17	Notaria 2a. de Barranquilla.	70,627		1997/07/31
2,281	1997/08/04	Notaria 2a. de Barranquilla.	70,813		1997/08/14
765	1999/04/22	Notaria 3a. de Barranquilla.	80,628		1999/04/23
459	2001/02/21	Notaria 2a. de Barranquilla.	91,502		2001/02/23
2,608	2001/10/05	Notaria 2a. de Barranquilla.	95,771		2001/11/08
1,730	2004/07/29	Notaria 2a. de Barranquilla.	112,999		2004/08/26
416	2005/03/03	Notaria 2a. de Barranquilla.	116,364		2005/03/10
1,613	2005/07/28	Notaria 2. de Barranquilla.	119,322		2005/08/18
710	2009/05/05	Notaria 3 a. de Barranquilla.	150,130		2009/06/30
1,054	2009/06/25	Notaria 3 a. de Barranquilla.	150,130		2009/06/30

C E R T I F I C A

Que de acuerdo con la(s) escritura(s) arriba citada(s), la sociedad se rige por las siguientes disposiciones:

DENOMINACION O RAZON SOCIAL:

PROCAPS S.A.

SIGLA: PROCAPS.

DOMICILIO PRINCIPAL: Barranquilla.

NIT No: 890.106.527-5.

MATRICULA MERCANTIL: 24,802.

Barranquilla, 15 de Sep/bre de 2009 Hr:15:56:28



***** Pag. 2

CAMARA DE COMERCIO
DE BARRANQUILLA

08*****

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

PROCAPS S.A.

NIT: 890.106.527-5

C E R T I F I C A

Direccion para notificaciones judiciales:

CL 80 No 78 B - 201

De la ciudad de Barranquilla.

C E R T I F I C A

DURACION: El término de duración de la sociedad se fijó hasta el 18 de Agosto de 2073

C E R T I F I C A

OBJETO SOCIAL: El objeto principal de la sociedad sera: a) La fabricacion, importacion y comercializacion de alimentos procesados y suplementos dietarios. b) La fabricacion de capsulas y otros productos similares a partir de materiales tales como gelatinas u otros de distinta naturaleza, que puedan ser utilizados como envases o recipientes de productos y sustancias quimicas, farmaceuticas, alimenticias y cosmeticas, para uso y consumo humano y veterinario. c) La investigacion, desarrollo y fabricacion de toda clase de productos y sustancias quimicas, farmaceuticas, alimenticias y cosmeticas para uso y consumo humano, animal y vegetal. d) La compra y venta de materias primas, insumos y productos intermedios necesarios para los procesos de fabricacion de sustancias quimicas, farmaceuticas, alimenticias y cosmeticas, asi como la comercializacion interna y externa de los productos terminados. e) La compra, venta, importacion, exportacion y distribucion de toda clase de elementos instrumentales y equipos medicos, quirurgicos, odontologicos y hospitalarios para la salud humana y animal. f) La compra, venta, exportacion, fabricacion, importacion, distribucion de dulces, confites, galletas y todo tipo de golosinas o alimentos para el consumo humano. g) Actuar como representante o agente de personas naturales y juridicas, nacionales y extranjeras en la realizacion de operaciones o transacciones relacionadas con la industria farmaceutica y en especial con cualquiera de las actividades descritas en los literales a), b), c), d) y e) antes descritos. h) Prestar los servicios de asesorias y consultoria en las areas administrativas, de mercadeo, analisis clinico, asistencia tecnica, investigacion, costos y produccion, exportaciones, importaciones, ventas, relacionadas con iguales o similares actividades a las que constituyen el objeto de PROCAPS S.A., asi como los de publicidad y promocion de productos quimicos, alimenticios, cosmeticos y

***** C O N T I N U A *****

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

PROCAPS S.A.
NIT: 890.106.527-5.

farmaceuticos para uso humano, animal o industrial. i) Adquirir, operar, administrar y explotar, a cualquier titulo, empresa o establecimientos dedicados a la investigacion, desarrollo, fabricacion o comercializacion de productos quimicos, farmaceuticos, alimenticios, hospitalarios o cosmeticos. En desarrollo de su objeto principal, la sociedad podra tomar interes social como accionista, socio o fundador de empresas que tengan igual o similar objeto, comprar, vender, importar y exportar maquinarias, insumos y repuestos requeridos para el desarrollo de sus actividades; tomar dinero en prestamo, financiar y garantizar las operaciones comerciales que celebre con terceros relativas a su objeto; celebrar y ejecutar todo tipo de actos y contratos necesarios para desarrollar sus operaciones; girar, aceptar, otorgar y protestar todo tipo de titulos valores e instrumentos negociables, comprar, vender y constituir gravámenes sobre bienes muebles e inmuebles, designar representantes apoderados en el pais y en el exterior y, (en general) realizar cualquier acto o negocio que sea necesario o conveniente para el desarrollo de su objeto social y para la mejor proteccion de sus intereses corporativos o la de sus socios. La sociedad podra garantizar el cumplimiento de sus obligaciones adquiridas por terceros o por sus socios, para lo cual podra inclusive constituir gravámenes reales sobre sus bienes de cualquier naturaleza.

C E R T I F I C A

CAPITAL	Nro Acciones	Valor Acción
Autorizado		
\$*****2,000,000,000	*****2,000,000	*****1,000
Suscrito		
\$*****1,229,071,000	*****1,229,071	*****1,000
Pagado		
\$*****1,229,071,000	*****1,229,071	*****1,000

C E R T I F I C A

ADMINISTRACION: La direccion y administracion de la sociedad corresponde a la Asamblea General de Accionistas, a la Junta Directiva al Presidente, al Vicepresidente y a un Gerente General. Corresponde a la Junta Directiva las siguientes funciones y atribuciones entre otras: Autorizar cualquier acto o contrato cuya cuantia sea superior al equivalente en pesos Colombianos a doscientos cincuenta mil dolares de los Estados Unidos de America (US\$250.000), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la transaccion. Cuando se trate de operaciones en virtud de las cuales la sociedad garantice obligaciones de terceros o de los socios, se requerira que la operacion sea aprobada con el voto de por lo menos 2/3 partes de los integrantes de la Junta Directiva. La sociedad tendra un Presidente, quien ejercera la representacion legal de la sociedad y tendra las siguientes atribuciones entre otras: Ejecutar las decisiones de la Asamblea General de Accionistas y de la Junta Directiva. Ejercer la Representacion Legal de la sociedad en todos los actos y contratos que se

***** C O N T I N U A *****



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requieran para el desarrollo del objeto social, de conformidad con lo previsto en las leyes y en los presentes estatutos. Constituir apoderados judiciales y extrajudiciales, recibir notificaciones, absolver interrogatorios de parte, confesar obligaciones de la sociedad, transigir, disistir y allanar a la sociedad en cualquier asunto judicial. Aprobar y celebrar en nombre de la socieda todo acto o contrato cuya cuantia sea igual o inferior al equivalente en pesos colombianos a doscientos cincuenta mil dolares de los Estados Unidos de America (US\$250.000), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la transacion o celebracion del acto. Las demas funciones que le correspondan como Representante Legal por disposicion de la ley, de estos estatutos o de la Junta Directiva. El Presidente tendra un suplente, designado por la Junta Directiva, quien reemplazara al Presidente en sus faltas temporales, absolutas o meramente accidentales, con entidades facultades y sin que sea necesario para ello acreditar la ausencia del principal. La sociedad tendra un Vicepresidente designado por la Junta Directiva, quien tambien ejercera la representacion legal de la sociedad, pudiendo ejercerla conjunta o separadamente con el Presidente. El vicepresidente tendra las siguientes facultades entre otras. Ejecutar dentro de su competencia las decisiones de la Asamblea General de Accionistas, de la Junta Directiva y del Presidente. Ejercer la representacion legal de la sociedad en todos los actos y contratos que se requieran para el desarrollo del objeto social, de conformidad con lo previsto en las leyes y en los presentes estatutos. Constituir apoderados judiciales y extrajudiciales, recibir notificaciones, absolver interrogatorios de parte, confesar obligaciones de la sociedad, transigir, desistir y allanar a la sociedad en cualquier asunto judicial. Aprobar y celebrar en nombre de la sociedad todo acto o contrato cuya cuantia sea igual o inferior al equivalente en pesos colombianos a ciento cincuenta mil dolares de los Estados Unidos de America (US\$150.000), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la aprobacion o celebracion del acto, siempre que no se trate de enajenar bienes inmuebles o cualquier otro activo fijo de la sociedad, inclusive de naturaleza muebles, acciones, cuotas o partes de interes inversiones y todo tipo de derechos de la sociedad, o de constituir gravámenes sobre cualquiera de los anteriores, facultades que radican exclusiva y privativamente en cabeza del Presidente. Las demas funciones que le corresponda como Representante legal por disposicion de la ley, de estos estatutos o de la Junta Directiva. El Vicepresidente tendra (1) suplente, designado por la Junra Directiva, quien lo reemplazara conjunta o separadamente en sus faltas temporales, absolutas o meramente accidentales, con identicas facultades y sin que sea necesario para

***** CONTINUA *****

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

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ello acreditar la ausencia del principal. La sociedad tendrá un (1) Gerente General, con su respectivo Suplente, designados por la Junta Directiva. El Suplente reemplazara al Gerente General, en sus faltas temporales, absolutas o meramente accidentales, quien junto con el gerente general, llevarán la representación legal de la sociedad, con idénticas facultades, pudiéndolas ejercer conjunta o separadamente con el Presidente y Vicepresidente, con idénticas facultades que el Gerente General y sin que sea necesario para ello acreditar la ausencia del titular. El Gerente General tendrá las siguientes facultades entre otras: Ejercer la representación legal de la sociedad, en todos los actos y contratos que se requieran para el desarrollo del objeto social, de conformidad con lo previsto en las leyes y en los presentes estatutos. Aprobar y celebrar en nombre de la sociedad todo acto o contrato cuya cuantía sea igual o inferior al equivalente en pesos Colombianos a Cincuenta Mil dólares de los Estados Unidos de America (US\$50.000), liquidados a la tasa de cambio representativa del mercado vigente el día en que se surta la aprobación o celebración del acto, siempre que no se trate de enajenar a cualquier título bienes inmuebles o cualquier otro activo fijo de la sociedad, inclusive de naturaleza mueble, acciones, cuotas o partes de intereses, inversiones y todo tipo de derechos de la sociedad o de constituir gravámenes sobre cualquiera de las anteriores facultades que radican exclusiva y privativamente en cabeza del Presidente.

C E R T I F I C A

Que según Acta No. 116 del 27 de Junio de 1997 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad:

PROCAPS S.A.

cuya parte pertinente se inscribió en esta Cámara de Comercio, el 15 de Agosto de 1997 bajo el No. 70,838 del libro respectivo, y según Acta No. 127 del 22 de Marzo de 2000 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad:

PROCAPS S.A.

cuya parte pertinente se inscribió en esta Cámara de Comercio, el 29 de Mayo de 2000 bajo el No. 87,250 del libro respectivo, fueron hechos los siguientes nombramientos:

CLASE: JUNTA DIRECTIVA

Principales

1. Minski Gontovnik Ruben
2. Minski Gontovnik Meyer
3. Minski Gontovnik Jose

CC.*****7,463,982

CC.*****7,461,324

CC.*****8,671,834

Suplentes

1. Minski Zirberblum Elliot
2. Minski Deitel Daniel
3. Minski Sharon

CC.*****72,219,541

PA.*990,212,082,805

C E R T I F I C A

Barranquilla, 15 de Sep/bre de 2009 Hr:15:56:28



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PROCAPS S.A.-----

NIT: 890.106.527-5.

Que según Acta No. 116 del 27 de Junio de 1997 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 15 de Agosto de 1997 bajo el No. 70,838 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre	Identificación
Presidente.	
Minski Gontovnik Ruben	CC.*****7,463,982
Suplente del Presidente	
Minski Minski Abraham	CC.*****802,575
Vicepresidente	
Minski Gontovnik Meyer	CC.*****7,461,324
Suplente del vicepresidente	
Minski Gontovnik Jose	CC.*****8,671,834

C E R T I F I C A

Que según Acta No. 11 del 01 de Febrero de 2001 correspondiente a la Junta Directiva en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 12 de Febrero de 2001 bajo el No. 91,273 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre	Identificación
Gerente General.	
Uribe Ochoa Guillermo Luis	CC.*****70,073,754

C E R T I F I C A

Que según Acta No. 406 del 02 de Sep/bre de 2004 correspondiente a la Junta Directiva en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 09 de Sep/bre de 2004 bajo el No. 113,263 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre	Identificación
Suplente del Gerente.	
Tanaka Tatekawa Walter	CC.*****16,251,923

C E R T I F I C A

Que según Acta No. 124 del 29 de Marzo de 1999 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 04 de Agosto de 1999 bajo el No. 82,226 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre	Identificación

***** C O N T I N U A *****

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PROCAPS S.A.

NIT: 890.106.527-5.

Revisor Fiscal Ppal.

Vargas Pertuz Ana Isabel

CC.*****32,696,645

C E R T I F I C A

Que según Acta No. 151 del 31 de Marzo de 2009 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 30 de Julio de 2009 bajo el No. 151,129 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre
Suplente del Revisor Fiscal.

Identificación

Duarte Diaz David

CC.*****73,115,965

C E R T I F I C A

Que por Escritura Pública No. 2,784 del 07 de Dic/bre de 2007, otorgada en la Notaria 2 a. de Barranquilla cuya parte pertinente se inscribió en esta Cámara de Comercio, el 20 de Dic/bre de 2007 bajo el No. 3,492 del libro respectivo, y las inscripciones 3.492-1, 3.493, 3.494, 3.495, 3.496, 3.497, 3.498, 3.499, 3.500, 3.501, 3.502, 3.503, 3.504, 3.505, 3.506, 3.507, Consta que RUBEN MINSKI GONTOVNIK, C.C. No. 7.463.982, obrando como Presidente y Representante Legal de la sociedad C.I. NATURMEGA S.A. que obrando en su condicion de Presidente y Representante Legal de la sociedad PROCAPS S.A., el presidente debidamente facultado por los Estatutos Sociales y por el Maximo Organo Social, otorga los siguientes poderes: Otorgar poder general, amplio y suficiente a los doctores JOSEFINA DEL CARMEN MIELES BUELVAS CC.No.33.138.497; a MARCELA CARVAJALINO PAGANO CC.No.22.579.748; CRISTINA VIOLI FRANCESCHINI CC.No.22.463.716, con las facultades que se transcriben a continuacion: a.- Para que representen a la sociedad PROCAPS S.A. ante todo tipo de autoridades administrativas y jurisdiccionales, en asuntos de naturaleza civil, laboral, comercial, penal, aduanera, cambiaria, tributaria, policiva, administrativa y fiscal. b.- Contestar y presentar demandas, requerimientos, recursos, pedir y aportar pruebas, recibir, notificarse, ejercer la accion de tutela, tramitar incidente de desacato, comparecer en los procesos que cursen contra la sociedad, allanarse en nombre de la sociedad en los asuntos que sean necesarios, transigir, desistir, sustituir, renunciar y reasumir el poder. c.- La facultad expresa de conciliar, por tanto pueden llegar a acuerdos conciliatorios, transaccionales, judiciales o extrajudiciales o extrajudiciales, cualquiera que sea su cuantia, para lo cual las apoderadas deben aportar la autorizacion simple y escrita del Representante legal de la sociedad. d.- Podran presentar solicitudes de devolucion y/o compensacion de impuestos, ventas y rentas, recibir los pagos por las devoluciones y adelantar todo tramite o proceso administrativo ante la DIAN, de tal forma que en ningún momento quede sin representacion legal de la sociedad. PODERES ESPECIALES: a.- Se confiere poder especial amplio y suficiente a las personas que se determinan seguidamente, que conforman el grupo A y B, para, para

***** C O N T I N U A *****



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que conjuntamente suscriban contratos de suministros de mercancías y servicios con entidades oficiales, hasta la suma de OCHOCIENTOS MIL DOLARES DE LOS ESTADOS UNIDOS DE AMERICA (US800.000.00), ----- liquidados a la tasa representativa del mercado vigente en el día

que se realice la respectiva transacción. Grupo A. WALTER NANAKA TATEKAWA CC.No.16.251.923, CLAUDIA TANGARIFE CASTILLO -----

CC.No.41.660.293, CARMEN ALICIA FLOREZ CC.No.22.434.044, IVAN VILLAREAL CAMACHO CC.No.91.201.749, CARMEN ALICIA HERRERA -----

DIAZGRANADOS CC.No.22.377.540, DAVID ANTONIO CHARRIS GIRALDO CC.No.19.341.274, RICARDO DORADO HURTADO CC.No.79.715.772, JAIME

FORERO LLINAS CC.No.19.300.593. b.- Se confiere poder especial amplio y suficiente al señor WILLIAM ALBERTO BARROS CERRA -----

CC.No.8.715.941, para que en nombre y representación de PROCAPS S.A. suscriban declaraciones cambiarias, aduaneras y tributarias a

que este obligada la sociedad, en el giro normal de sus negocios y operaciones sociales, por tanto quedan facultados para firmarlas,

como también los demás documentos relacionados con ellas, notificarse, aportar y solicitar las pruebas que sean necesarias.

c.- Otorgar poder especial amplio y suficiente al señor MARLON TATIS PAREDES CC.No.72.176.874 y al señor WILLIAM ALBERTO BARROS CERRA CC.No.8.715.941, para que en nombre y representación de

PROCAPS S.A., suscriban las declaraciones, reportes y cualquier documento relacionado con los trámites o registros de Comercio Exterior y o cualquier entidad del Estado que haga sus veces: d)

Otorgar poder especial amplio y suficiente a la doctora CARMEN ALICIA HERRERA DIAZGRANADOS, CC.No.22.377.540 y al doctor WALTER TANAKA TATEKAWA, CC.No.16.251.923, para que en nombre y

representación de PROCAPS S.A.; endosen los títulos valores de la sociedad hasta por la suma de UN MIL MILLONES DE PESOS (1.000.000.000.00) M.L. CUARTO: El representante legal de la

sociedad PROCAPS S.A.; doctor RUBEN MINSKI GONTOVNIK, manifiesta que la presente reforma fue aprobada por la Asamblea General Extraordinaria de Accionista de PROCAPS S.A., con observancia de

las disposiciones legales y estatutarias.-----

C E R T I F I C A

Que por Escritura Pública No. 1.933 del 16 de Sep/bre de 2008, otorgada en la Notaria 2 a. de Barranquilla cuya parte pertinente se inscribió en esta Cámara de Comercio, el 06 de Octubre de 2008 bajo el No. 3,748 del libro respectivo,-----

Consta que el señor RUBEN MINSKI GONTOVNIK, C.C. No. 7.463.982, que comparece en su condición de Presidente y Representante Legal de la Sociedad PROCAPS S.A., confiere por medio de este instrumento publico Poder especial Amplio y Suficiente a la doctora MILENA -----

***** C O N T I N U A *****

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

PROCAPS S.A.

NIT: 1890.106.527-5.

ESCAFFI PARDO, C.C. No. 32.758.420, para que en nombre y representación de PROCAPS S.A., suscriba declaraciones cambiarias, aduaneras y tributarias a que este obligada la sociedad en el giro normal de sus negocios y operaciones sociales, por tanto queda facultada para firmar, como tambien los demas documentos relacionados con ellas, notificarse, aportar y solicitar las pruebas que sean necesarias.

C E R T I F I C A

Que en esta Cámara de Comercio no aparecen inscripciones posteriores de documentos referentes a reforma, disolución, liquidación o nombramientos de representantes legales de la expresada sociedad.

C E R T I F I C A

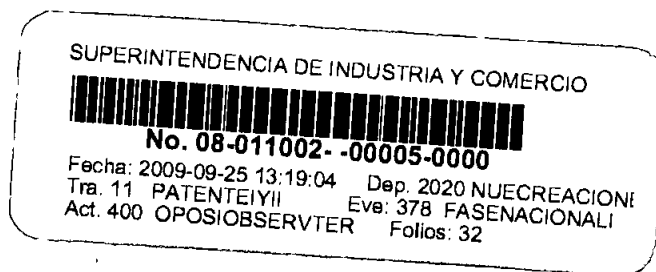
Que su última Renovación fue el: 27 de Marzo de 2009.

La información sobre embargos de establecimiento se suministra en Certificados de Matrícula, la de contratos sujetos a registro, en Certificados Especiales.

C E R T I F I C A

Que los actos de registro aquí certificados quedan en firme cinco días hábiles después de la correspondiente inscripción siempre que, dentro de dicho término, no sean objeto de los recursos de reposición ante esta entidad y/o de apelación para ante la Superintendencia de Industria y Comercio.

m. l. g. j. a. s.



SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 09 - 72,143
FECHA : SEPTIEMBRE 25 DE 2009

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
LAB. PROCAPS	CONSIGNACION	BANCO DE BOGOTA	062754387	129944592	31/08/2009	1,148,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-04	PRESENTACION DE OBSERVACIONES	
12		MARCAS Y LEMAS COMERCIALES	287,000.00
		TOTAL :	\$ 287,000.00

SON: DOSCIENTOS OCHENTA Y SIETE MIL PESOS

RESPONSABLE :

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____



US006150399A

United States Patent [19]

Patel et al.

[11] **Patent Number:** **6,150,399**[45] **Date of Patent:** **Nov. 21, 2000**[54] **SOY-BASED NUTRITIONAL PRODUCTS**

[75] Inventors: **Gauravkumar C. Patel**, Gahanna;
Michael Allen Chandler; **Kent Lee**
Cipollo, both of Westerville; **Lisa**
Diane Craig, Columbus; **Theresa W.**
Lee, Upper Arlington, all of Ohio

[73] Assignee: **Abbott Laboratories**, Abbott Park, Ill.

[21] Appl. No.: **09/107,886**

[22] Filed: **Jun. 30, 1998**

[51] **Int. Cl.**⁷ **A61K 31/35**; A61K 9/68;
A23L 2/38; A23J 1/00; A23J 1/36

[52] **U.S. Cl.** **514/456**; 426/598; 426/72;
426/74; 426/656; 426/629; 424/440

[58] **Field of Search** 424/440; 426/656,
426/629, 598, 72, 74; 514/456

[56] **References Cited****U.S. PATENT DOCUMENTS**

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5,186,963	2/1993	Howman	426/72
5,277,910	1/1994	Hidvegi	424/195.1
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Kurzer and Xu, "Dietary Phytoestrogens," *Annu. Rev. Nutr.*, 1997, 17, pp. 353-381.

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GeniSoy™ Product Literature, May 8, 1998.

Ross Medical Nutritional System Product Handbook, 1996, pp. 2, 4, 28, 36, 66.

Ross Pediatric Nutritional Product Guide, 1997, pp. 36-37.

Ross Medical Nutritional Products, Optimental™, 1998, pp. 1-8.

Primary Examiner—Theodore J. Criares

Assistant Examiner—Jennifer Kim

Attorney, Agent, or Firm—Thomas D. Brainard; Nickki L. Parlet; J. Michael Dixon

[57] **ABSTRACT**

The present invention relates generally to a complete nutritional product that provides soy protein and enhanced levels of isoflavones. Preferably, the soy protein comprises at least 0.7 mg isoflavones / gm soy protein and at least 0.5 mg genistein / gm soy protein. The product is fortified at 35% of the RDI for calcium and contains an antioxidant package. The invention also describes the method to produce a heat stable isoflavone-enriched soy protein complete nutritional.

19 Claims, No Drawings

SOY-BASED NUTRITIONAL PRODUCTS

TECHNICAL FIELD

The present invention relates generally to a low fat, vitamin/mineral fortified soy-based oral nutritional product useful for providing soy protein in addition to the inherent isoflavones to a health conscious population.

BACKGROUND OF THE INVENTION

Substitution of vegetable protein for animal protein in an individual's diet has traditionally addressed the needs of persons with food allergies or intolerance to dairy-based formula components (usually casein, whey, or lactose) and individuals who desire to limit or avoid animal protein for life style philosophy (vegetarianism) or religious beliefs and practices. As positive outcomes from research in the area of vegetable extracts in the nutritional management of disease states are published, desire to add these "added value" vegetables to individual diets has expanded in the general population.

Many of the "active components" identified in vegetables are phytoestrogens. A number of these compounds have been identified in fruits, vegetables, and whole grains commonly consumed by humans. Phytoestrogens include isoflavones which occur in a variety of leguminous plants. Soybeans are the most significant dietary sources of isoflavones. Isoflavones have been detected and identified in biological fluids of humans consuming the plant material. Due to the phenolic structure, which is similar to those of animal estrogens, these compounds exhibit weak estrogenic properties and are termed phytoestrogens. It is the isoflavones which have received the most attention and have been reviewed in great detail in "Mammalian lignans and phytoestrogens- Recent studies on their formation, metabolism and biological role in health and disease" by Setchell and Adlercreutz, *Role of the Gut Flora in Toxicity and Cancer*. New York, Academic Press, 1988; pp 315-45; "Naturally Occurring Oestrogens in Foods- A Review" by Price and Fenwick, *Food Additives and Contaminants*, Vol.2, No.2, pp73-106,1985; and "Dietary Phytoestrogens" by Kurzer and Xu, *Annual Review of Nutrition* Vol 17, 1997; pp 353-81.

Studies in humans, animals and cell culture systems suggest that dietary phytoestrogens play an important role in prevention of menopausal symptoms, osteoporosis, cancer, and heart disease. Proposed mechanisms include estrogenic and antiestrogenic effects, induction of cancer cell differentiation, inhibition of tyrosine kinase and DNA topoisomerase activities, suppression of angiogenesis and antioxidant effects. The major isoflavones occurring in plants are the glycosides of genistein, daidzein and glycitein.

Isoflavones isolated from soy have become the focus of much research in the areas of heart disease, cancer, osteoporosis and kidney diseases. This expanding knowledge in the possible role of soy and its fractions in the nutritional management of disease states has presented practical challenges for the average consumer in the market place. The primary challenge is access to good tasting products with naturally high concentrations of isoflavones.

The isoflavone contents in commercial soy raw ingredients vary depending on the levels of isoflavones in the plant variety and processing procedures. For example, approximately 90% of phytoestrogens present in soy foods are beta-glucoside conjugates of daidzein and genistein. However, in fermented soy products, the aglucones (unconjugated) are the predominant forms. The nutrient and

isoflavone content of the most common available soy foods, soy ingredients and nutritional are listed in Table 1 below.

TABLE 1

Nutrient and Isoflavone Content of Different Soy Foods and Ingredients*

Soy food	Calories Kcal	Protein g (% of Cal.)	Fat g (% of Cal.)	Estimated Isoflavone mg
Miso (1 oz)	35	2 (23)	1 (25)	10
Soybeans, cooked (1/2 cup)	149	14 (37)	8 (48)	35
Soy flour (3 1/2 cup)	441	35 (32)	22 (45)	50
Soymilk (1 cup)	140	10 (28)	4 (26)	40
Soymilk, low-fat (1 cup)	120	8 (26)	3 (22)	40
Soy nuts, dry roasted (1/2 cup)	387	34 (35)	19 (44)	50
Soy protein isolate (1 oz)	94	25 (100)	1 (9)	15
Tempen (4 oz)	204	17 (33)	8 (35)	40
Tofu, low-fat (3 oz)	35	6 (68)	1 (25)	30
Tofu, extra-firm (3 oz)	60	6 (40)	3 (45)	45
Textured Vegetable Protein (1/4 cup, dry)	59	11 (74%)	0 (0)	35
Ensure (8 fl. oz.)	250	8.8 (14)	6.1 (22)	2.6
GeniSoy (35 gm)	130	14 (43)	0 (0)	14-70**

*Table adapted from US Department of Agriculture Handbook 8

**Based on GeniSoy literature which describes a typical isoflavone range from 1.0-5.0 mg isoflavone/gram soy protein, assuming 100% of the protein is soy protein containing isoflavone.

While there are a few soy-based foods available on the market today, they are not easily incorporated into an individual's diet. Accessibility of the products listed in Table 1 is an issue for most of the general population. A few of the products are starting to be stocked in standard grocery stores; however, many must be purchased in "Health Food Stores". More importantly, the taste and texture of soy products are objectionable to many individuals that have not grown up with soy protein in their diets. In addition, most of the foods in Table 1 are ingredients to be incorporated into a food dish and most individuals do not know how to cook with these ingredients. While the roasted soy nuts, which would probably be an acceptable snack food for most individuals, weigh in with a high isoflavone content, the high calorie and fat content are unacceptable for daily incorporation into an individual's diet. Soy milk is a reasonable source of isoflavones and has been used by individuals with cow milk allergies for many years and there are currently more flavors and fat content options to chose from. A serving (1 cup) of "Light" soy milk contains 3 grams of fat and 8 grams of protein in 120 total calories. No inherent vitamins and a small amount of calcium and iron (2% of the RDI) are present in soy milk. A serving (1 cup) of full fat soy milk contains 4 grams of fat and 10 grams of protein in 140 total calories. The requirement for refrigerated storage and the flavor of soy milk remain a major obstacle for the average consumer.

FDA-regulated food products began using the Daily Value as the basis for declaring nutrient content May 8, 1994. Daily Values (DVs) are a set of dietary reference values to help consumers use food label information to plan a healthy overall diet. DVs actually comprise two sets of reference values for nutrients: Daily Reference Values (DRVs) and Reference Daily Intakes (RDI).

DRVs are a set of dietary references for which no set of standards previously existed. DRVs apply to fat, saturated fat, cholesterol, carbohydrate, protein, fiber, sodium and potassium. Based on 2,000 calories a day for adults and children over 4, the DRV for fat is 65 grams; saturated fat is 20 gm; cholesterol is 300 milligrams; total carbohydrate is 300 grams; fiber is 25 grams; sodium is 2,400 milligrams; potassium is 3,500 milligrams; and protein is 50 grams.

RDI's are a set of dietary references based on the Recommended Dietary Allowances (RDA) for essential vitamins and minerals. The name "RDI" replaces the term "U.S. RDA" (Recommended Daily Allowances). Recommended Dietary Allowances (RDA) are the set of estimated nutrient allowances established by the National Academy of Sciences used as the basis for setting the U.S. RDAs. It is updated periodically to reflect current scientific knowledge.

The liquid nutritional, Ensures (Ross Products Division of Abbott Laboratories, Chicago, Ill.), a good tasting, shelf stable, ready to drink complete nutritional with a protein system that contains soy protein isolate, is an alternative to the more traditional soy foods. However, only 20% of the total protein system is soy protein isolate resulting in an isoflavone content too low to practically provide the benefit of consuming soy protein.

GeniSoy™ is a powdered protein shake manufactured by GeniSoy Products Co. (Fairfield, Calif.) with water processed isolated soy protein. A serving (8 oz.) of the Vanilla product contains 14 gm of soy protein, zero fat and 18 gm of total carbohydrate in 130 calories. The vitamins and minerals are fortified at 25% of the RDI with the exception of vitamin E (170% of the RDI). GeniSoy Products literature states that although the isoflavone content of GeniSoy is not tested, typical isoflavone values for water processed soy protein isolate range from 1.0 to 5.0 mg of isoflavone/gram soy protein isolate. While this vitamin and mineral fortified product provides large amounts of soy protein isolate in a single serving, it is not a complete nutritional that could be used as a sole source of nutrition due to the absence of fat in the form of essential fatty acids. Further, the inconvenience of the powder form and the soy flavor remain an issue for many consumers.

Isoflavone compounds are associated with the inherent bitter flavor of soybeans. Consequently, in the production of commercial products, such as isolates and concentrates, the focus has been traditionally to remove these materials. For example, in a conventional process for the production of a soy protein isolate, in which soy flakes are extracted with an aqueous alkaline medium, much of the isoflavones are solubilized in the extract, and remain solubilized in the whey, which is usually discarded following acid precipitation of the protein to form an isolate. Residual isoflavones left in the acid precipitated protein isolate are usually removed by exhaustive washing of the isolate. This process has been modified to maintain and enrich the isoflavone content of the vegetable isolates, concentrates, protein fiber and whey.

EP 0 647 408 by Shen, et al., teaches how to manufacture an isoflavone enriched vegetable protein isolate by extracting a vegetable protein material containing isoflavones at a pH above the isoelectric point of the material, then adjusting the pH to about the isoelectric point of the protein material resulting in a precipitate, then doing limited washing of the precipitate to provide an isoflavone enriched protein isolate.

U.S. Pat. No. 5,637,562 by J. L. Shen discloses a process to manufacture isoflavone enriched vegetable protein concentrate through an isoelectric wash of a vegetable protein

material to provide a protein concentrate, which is slurried and reacted with a sufficient amount of beta-glucosidase enzyme or esterase enzyme for a time period, temperature and pH sufficient to convert at least a majority of the glucone isoflavones contained in the concentrate to aglucone isoflavones.

U.S. Pat. No. 5,352,384 by J. L. Shen discloses a process to manufacture isoflavone enriched vegetable protein fiber. The starting material is extracted at a pH above the isoelectric point of the protein material, the aqueous slurry containing the solubilized isoflavones is reacted with a beta-glucosidase to convert the isoflavones in glucone form to an aglucone isoflavone making the isoflavones less soluble, the fibrous residue is recovered to provide a vegetable fiber product which has been enriched with aglucone isoflavones.

U.S. Pat. No. 5,637,561 by J. L. Shen discloses a process to make aglucone isoflavone enriched vegetable protein whey by treating the whey stream, comprising glucone isoflavones, with a sufficient amount of beta-glucosidase enzyme or esterase enzyme or acid to convert at least a majority of the glucone isoflavones to aglucones thereby providing an aglucone enriched whey stream. The aglucone enriched whey protein is obtained by recovery of the protein.

The importance of isoflavone enriched vegetable protein sources becomes more apparent when one reviews the field of isoflavone research. Most of the human research on isoflavones has been carried out by incorporating soy products into the typical American diet or studying Asian countries where soy is a normal part of the diet. While the health benefits of soy have been attributed to isoflavones, the actual active ingredient or ingredients have yet to be identified. The level and ratio of the isoflavones in addition to other inherent components of soy may play an important role in the health benefits attributed to soy. However, there are dietary supplement patents incorporating isolated phytoestrogens into compositions for the management of osteoporosis and premenstrual syndrome.

A product containing isoflavones for the management of osteoporosis is described in U.S. Pat. No. 5,424,331 by M. Shlyankevich which discloses a pharmaceutical or dietary supplement for the treatment or prevention of osteoporosis. The composition comprises phytoestrogen compounds; dried licorice root extract; calcium, magnesium and zinc salts; beta carotene; and vitamin D and E in an acceptable inert carrier.

A product containing isoflavones for the management of premenstrual syndrome is described in U.S. Pat. No. 5,569,459 by M. Shlyankevich which discloses a pharmaceutical or dietary supplement for controlling the stimulation of estrogen production. The composition comprises phytoestrogen compounds; dried licorice root extract; a sedative selected from the group consisting of Balerian root dry extract, passion flower dry extract and Ginseng root powder; beta-carotene; pyridoxine hydrochloride; Vitamin E; calcium, magnesium and zinc salts; coumestan; and pantothenic acid in an acceptable inert carrier.

A dietary supplement for supplementing the nutritional needs of women and preventing or reducing life stage associated health risks during each of their principal adult life stages (pre-perimenopause, perimenopause and menopause, or post-menopause) is described in U.S. Pat. No. 5,654,011 by S. D. Jackson, et al. The dietary supplement comprises calcium, magnesium, boron, copper, manganese, zinc, vitamin D, E and C; iron, folic acid, vitamin B₁₂ and B₆; chromium, and phytoestrogens in a biologically acceptable carrier.

As discussed above, there are several soy-based products currently available to the consumer. However, they are products with unacceptable taste or mouth feel, they require special storage conditions such as refrigeration or are in powder forms requiring an additional reconstitution step before consumption. Further limitations of these products appear in their nutrient content. Their nutrient content ranges from no supplementation of vitamins and minerals to fortification at 25% of the RDI. These soy based products have not been optimized to complement the positive effects attributed to soy such as, for example, fortification of the formula to provide a calcium/phosphorous ratio sufficient to complement the effects of soy on osteoporosis; or a sodium limitation for the hypertensive individual; or an antioxidant package to complement the cancer and heart disease benefits of soy.

Clearly, there is need for a convenient, shelf stable, low fat, calcium enriched, good tasting, complete nutritional which is a soy-based product that will deliver inherent isoflavones to an individual choosing to supplement their diet with soy protein.

SUMMARY OF THE INVENTION

The present invention relates generally to a shelf stable, low fat, vitamin and mineral fortified soy-based complete liquid nutritional product useful for providing soy protein and its inherent isoflavones to an individual.

One aspect of the invention is a complete liquid nutritional product containing a protein system providing from about 17% to about 25% of the total calories of the product, preferably from about 19% to about 23% of the total calories of the product; a lipid system which provides from about 5% to about 15% of the total calories of the product, preferably from about 10% to about 14% of the total calories of the product; a carbohydrate system which provides from about 56% to about 68% of the total calories of the product, preferably from about 57% to about 65% of the total calories of the product; and a vitamin and mineral system in quantities sufficient to make the product a complete nutritional, preferably at least 20% of the RDI in a single serving. The liquid nutritional product has a caloric density from about 0.6 kcal/ml to about 1.1 kcal/ml, preferably from about 0.8 kcal/ml to about 1.0 kcal/ml.

The protein system contains from about 30% to 100% (%wt.) soy protein, preferably from about 50% to 100% soy protein. The soy protein is selected from the group including soy flakes, soy protein isolate, soy protein concentrate, hydrolyzed soy protein, soy flour, soy protein fiber, soy whey and mixtures thereof. Preferably, the soy protein comprises at least 0.7 mg isoflavones / gm soy protein and at least 0.5 mg genistein / gm soy protein, more preferably at least 1.2 mg isoflavones / gm soy protein and at least 0.8 mg genistein / gm soy protein.

The lipid system may be selected from the group including high oleic safflower oil, soy oil, fractionated coconut oil, high oleic sunflower oil, corn oil, canola oil and mixtures thereof. Preferably, the lipid system is a blend of 20% corn oil, 40% high oleic safflower oil and 40% canola oil.

The carbohydrate system may be selected from the group including hydrolyzed corn starch, maltodextrin, glucose polymers, sucrose, corn syrup solids, glucose, fructose, lactose, high fructose corn syrup, fructooligosaccharides and mixtures thereof. Preferably, the carbohydrate system comprises from about 35% to 52% of total carbohydrate as corn syrup, from 0 to about 22% of total carbohydrate as maltodextrin and from about 43% to 48% of total carbohydrate as

sucrose, more preferably, from about 35% to 40% of total carbohydrate as corn syrup, from 15% to about 22% of total carbohydrate as maltodextrin and from about 43% to 45% of total carbohydrate as sucrose.

The vitamin and mineral system for this complete nutritional comprises the vitamins A, B₁, B₂, B₆, B₁₂, C, D, E, K, beta-carotene, Biotin, Folic Acid, Pantothenic Acid, Niacin, Choline; the minerals calcium, magnesium, potassium, sodium, phosphorous, chloride; the trace minerals iron, zinc, manganese, copper, iodine; and the ultratrace minerals chromium, molybdenum and selenium. Preferably the calcium is fortified at 35% of the RDI in a single serving.

A second aspect of the invention is a method for providing soy protein containing inherent isoflavones, specifically genistein, to an individual by feeding the liquid nutritional product described above.

During the process of formulating the soy-based nutritional of the invention, unexpected stability challenges were addressed. A third aspect of the invention is the method of stabilizing a calcium enriched soy-based nutritional. The calcium enriched soy-based product comprises an isoflavone enriched soy protein, calcium fortified at 35% of the RDI with no more than 100 ppm soluble calcium and a stabilizer system to help suspend the insoluble minerals. Insoluble calcium sources are preferred to prevent the destabilization during sterilization of the soy protein by the soluble divalent minerals. Preferably the insoluble calcium sources are selected from soy-protein-bound-calcium and calcium citrate. More preferably, the soy-protein-bound-calcium contributes 85% of the total calcium and calcium citrate contributes 14% of total calcium. The stabilizer system consisting of cellulose gel and carrageenan provides for suspension of minerals; improved product physical stability; and improved organoleptic characteristics. Preferably, the stabilizer system comprises from about 1500 to about 2500 ppm cellulose gel and from about 150 to about 300 ppm carrageenan.

The stabilizing method further comprises the selection of a carbohydrate system consisting of maltodextrin, corn syrup and sucrose which expands the final product pH range of stability (6.6 to 7.2) while optimizing final product mouth feel. This carbohydrate system provides for a more durable formulation that can adapt to the variability seen in the stability of isoflavone enriched soy protein sources. The preferred carbohydrate system comprises from about 35% to about 52% of total carbohydrate as corn syrup, from 0 to about 22% of total carbohydrate as maltodextrin and from about 43% to about 48% of total carbohydrate as sucrose. Other aspects of the invention are described throughout the application.

DETAILED DESCRIPTION OF THE INVENTION

Any reference in this patent application to the "RDI for vitamins and minerals" refers to the list published in the 1993 Federal Register, Vol. 58. RDIs are a set of dietary references based on the Recommended Dietary Allowances (RDA) for essential vitamins and minerals. The name "RDI" replaces the term "U.S. RDA" (Recommended Daily Allowances). Recommended Dietary Allowances (RDA) are the set of estimated nutrient allowances established by the national Academy of Sciences used as the basis for setting the U.S. RDAs. It is updated periodically to reflect current scientific knowledge.

The term "total calories" refers to the total caloric content of a predetermined volume of the finished nutritional prod-

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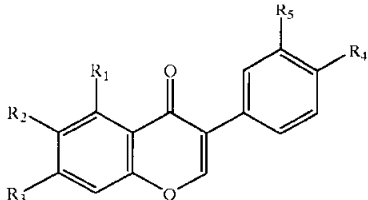
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uct. For example, a product with 12.5 gm of protein, 3 gm of fat and 33 gm of carbohydrate has 209 total calories per 237 ml.

The term "isoflavones" refers to the compounds having the following general formula, with specific compounds identified in Table 2.

TABLE 2

Chemical structures of isoflavones found in soybeans.



Isoflavone	R ₁	R ₂	R ₃	R ₄	R ₅
Daidzein	H	H	OH	OH	H
Genistein	OH	H	OH	OH	H
Glycitein	H	OCH ₃	OH	OH	H
Daidzin	H	H	O-glucoside	OH	H
Genistin	OH	H	O-glucoside	OH	H
Glycitin	H	OCH ₃	O-glucoside	OH	H

As described in Table 2, daidzin, genistin and glycitin are the beta-glucoside conjugate (glucosides) moieties. Daidzein, genistein and glycitein are the unconjugated (aglucones) moieties. As used herein "daidzein, genistein and glycitein levels" include both the conjugated and unconjugated moieties. The typical ratio of genistein to daidzein to glycitein in soy protein is 67 to 30 to 3.

The term "soy protein or soy protein source" refers to any protein form isolated from soybeans including, for example, soy flakes, soy protein isolate, soy protein concentrate, hydrolyzed soy protein, soy flour and soy protein fiber.

The term "standard genistein" soy protein refers to soy proteins that contain from about 0.5 to about 1.0 mg genistein per gram of soy protein.

The term "high genistein soy protein" and "isoflavone enriched soy protein" refers to soy proteins that contain at least 1.0 mg genistein per gram of soy protein.

The term "total isoflavone content" refers to the total amount of genistein, daidzein, glycitein and their glucoside moieties.

The term "complete nutrition" refers to a product that may be used as the sole source of nutrition. A complete nutritional provides 8 to 14 gm of protein; 3 to 10 gm fat; 30 to 40 gm carbohydrate; and 20 to 40% of the RDI for vitamins and minerals in 8 fl. oz or about 240 ml.

The term "single serving" refers to approximately 8 fl. oz or about 240 ml.

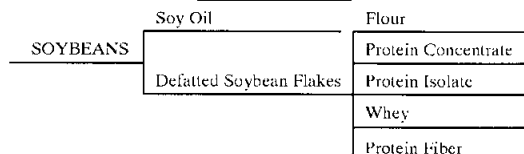
It is a principal object of the invention to provide an improved soy-based food for individuals who wish to add soy to their diets. The invention is to provide a shelf stable, low fat, good tasting liquid food composition which utilizes a soy protein system containing inherent levels of isoflavones, provides antioxidants and is a good source of calcium. Another object of this invention is to provide a method for stabilizing a calcium enriched soy-based nutritional.

The nutritional formulas of this invention will typically provide the following caloric distribution. The protein sys-

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tem will typically provide from about 17% to about 25% of total calories, more preferably from about 18% to about 24% of total calories. The fat system will provide from about 5% to about 15% of total calories, more preferably about 10% to about 14% of total calories. The carbohydrate system will typically provide from about 56% to about 68% of total calories, more preferably from about 57% to about 65% of total calories. The caloric density is typically from about 0.60 kcal/ml to about 1.10 kcal/ml, preferably from about 0.80 kcal/ml to about 1.0 kcal/ml.

One component of the nutritional formula of this invention is soy protein. As described above, a number of soy protein sources may be considered. The soy protein is isolated from the soybean. The soybean is an excellent source of high quality protein where about 38% to 40% of the soybean is protein. Briefly (as shown in Scheme 1), the processing of soybeans involves the extraction of the oil from the dehulled, and cracked soybeans leaving the defatted soybean flakes.

Scheme 1
Soybean Processing

The defatted soybean flakes are typically milled into flours; alcohol-extracted or alkaline/H₂O extracted to remove flavor compounds and sugars to make protein concentrates; and processed with water to remove sugars and flavor compounds, precipitated and dried to make protein isolates. Whey and protein fiber are by-products of the above processes. The preferred soy protein is processed in a manner to enrich the isoflavone content so that total isoflavone content (glucose and aglucone forms of genistein+daidzein+glycitein) is at least 0.7 mg isoflavones/gram soy protein. Further, the genistein content of the soy protein is at least 0.5 mg genistein/ gram soy protein. Acceptable soy protein sources are listed in the attached Examples. Preferred methods to produce isoflavone enriched vegetable protein were discussed briefly in the Background when reviewing production methods of isoflavone enriched soy protein described in EP 0 647 408, U.S. Pat. No. 5,637,562, U.S. Pat. No. 5,352,384, and U.S. Pat. No. 5,637,561 all by J. L. Shen.

The method used to analyze isoflavones in the final product utilizes the published extraction procedure of Murphy et al., Isoflavones in Soy-Based Infant Formulas, *Journal of Agricultural and Food Chemistry*, Vol 45, 1997, pp. 4635-4638. The non-polar nature and the intense UV absorptivities of these compounds make reversed phase HPLC a suitable approach for their determination in a variety of foods. An acidic 50/50 acetonitrile/water solution is used to extract the isoflavones from lyophilized product. The filtered extract is diluted with a buffered beta-glucuronidase solution, which rapidly affects the conversion of all conjugated forms (the "glucosides") of each isoflavone to the unconjugated form (the "aglucones" daidzein, genistein and glycitein). The aglucones are then separated by reversed phase chromatography, and detected by UV absorbance at 250 nm (daidzein) and at 262 nm (genistein). The aglucone concentrations are then determined by peak area proportionation versus solutions of specialized chemical

reference standards of known concentrations. Glycitein values are estimated from the genistein standard response at 262 nm as there is no glycitein standard available.

Soy proteins enriched with isoflavones have proven to be less heat stable than the regularly processed soy protein. The presence of soluble divalent minerals in the final product destabilizes the protein upon terminal sterilization. Consequently, the preferred soy protein source contains calcium in a colloidal suspension with the protein. U.S. Pat. No. 4,642,238 by H. C. Santz, et al., teaches how to produce a mineral enriched protein by combining a hydrated gel of an alkaline earth salt with soy protein isolate to form a mineral enriched soy protein composition. Preferably, about 85% of the total calcium is contributed by calcium bound to the soy protein and about 14% of total calcium is supplied by calcium citrate (insoluble calcium). Soluble calcium levels are no more than about 0.1% (100 ppm), preferably no more than 0.01% (10 ppm). Soluble calcium levels over 100 ppm destabilize the soy proteins during terminal sterilization.

The second component of the nutritional products of this invention is the fat system. As stated above, from about 5% to about 15% of the total calories of the nutritional products of the present invention are provided by this fat system. Any of the typical fat sources could be used such as high oleic safflower oil, soy oil, fractionated coconut oil, high oleic sunflower oil, corn oil, canola oil and mixtures thereof. The preferred fat system is a blend of 40% high oleic safflower, 40% canola oil and 20% corn oil. This fat blend, at these levels, permits the product to meet the recommendations of the American Heart Association for less than 30% of total dietary calories from fat, less than 10% of total calories from saturated fat, and no more than 10% of total calories from polyunsaturated fat. This blend also meets the recommendation of a ratio of n-6 to n-3 fatty acids of between 4:1 and 10:1. The lipid system will also typically contain a blend of oils designed to provide all of the essential fatty acids required to prevent malnutrition. The essential fatty acid, linoleic acid, can be provided by incorporating canola oil and soy bean oil into the formula. Other sources of these essential fatty acids are well known in the art and include borage, black currant seed, corn, marine oils, fungal oils, safflower, high oleic safflower, sunflower, high oleic sunflower, evening primrose, cottonseed, rice bran, grapeseed, flaxseed, garlic, peanuts, almonds, walnuts, wheat germ, egg, and sesame. To avoid essential fatty acid deficiency issues with sole source nutrition applications, the levels of linoleic acid (18:2n6) were chosen to deliver about 1 to about 3% of total energy based on a volume of nutritional product of about 1500 ml.

The third component of the nutritional products of this invention is a source of carbohydrates. The carbohydrates that may be used in the nutritional formula can vary widely. Examples of suitable carbohydrates that may be utilized include hydrolyzed corn starch, maltodextrin, glucose polymers, sucrose, corn syrup solids, glucose, fructose, lactose, high fructose corn syrup and fructooligosaccharides.

As noted above, the carbohydrates provide from about 56% to about 68% of the total calories of formula. Any single carbohydrate listed above, or any combination thereof, as appropriate may be utilized to provide these calories. The preferred carbohydrate system has been designed to optimize protein stability, mouth feel, and balance the palatability of the nutritional formula with the total calories contributed by simple sugars. The preferred carbohydrate source is a 35% of total carbohydrate corn syrup / 22% of total carbohydrate maltodextrin mixture with 43% of total carbohydrate as sucrose.

Maltodextrins and corn syrup solids are complex carbohydrates routinely used in nutritional formulations because of their excellent digestibility and functional properties. Specifically, they are good water binders and provide products with desired texture and mouth feel. Maltodextrins are polysaccharides obtained from the acid or enzyme hydrolysis of corn starch. Their classification is based on the degree of hydrolysis and is reported as dextrose equivalents (DE). The FDA defines maltodextrins as non-sweet, nutritive polysaccharides that have a DE less than 20. Corn syrup solids are defined as having DE's greater than 20. Corn syrup solids consist of dextrose chains about 3 to 4 units long while the maltodextrin used in the present invention (Lodex 15) is less hydrolyzed and contains polymers of 5 to 6 dextrose units. Polymer length is a major difference between corn syrup (DE 29) and Lodex 15 (DE 18). The difference in polymer length results in different functionality.

In the present invention, the use of corn syrup as a partial substitute for the maltodextrin results in a product that remains stable over a broader pH range. Specifically, product with corn syrup from about 35% to about 52% of the total carbohydrates was very stable from a pH range from about 6.6 to about 7.2. The broader pH range provides for a more durable formulation that can easily accommodate stability variability in the isoflavone enriched soy protein.

Substitution of corn syrup for maltodextrin to maximize product stability negatively impacts product mouth feel. Maltodextrins are often used as fat replacers because of their ability to provide texture and mouth feel. These sensory attributes are diminished when the maltodextrin is completely replaced by corn syrup but to a much less extent when only partially substituted as in the preferred carbohydrate blend.

The fourth component of the nutritional products of the present invention includes supplemented vitamins and minerals. The vitamin and mineral profile provides 20% to 30% of the RDI for vitamins and minerals in a single serving. Preferably, the nutritional products are designed so that two eight fluid ounce servings, approximately 480 ml, will provide at least 50% of the recommended daily intake (RDI) of vitamins and minerals.

The vitamin and mineral system for the complete nutritional of the invention comprises the vitamins A, B₁, B₂, B₆, B₁₂, C, D, E, K, beta-carotene, Biotin, Folic Acid, Pantothenic Acid, Niacin, and Choline; the minerals calcium, magnesium, potassium, sodium, phosphorous, and chloride; the trace minerals iron, zinc, manganese, copper, and iodine; and the ultratrace minerals chromium, molybdenum, selenium. Desirably, the nutritional products will include antioxidants such as a combination of beta-carotene, vitamin E and C at about 50% of the RDI per single serving.

Further the preferred nutritional product provides about a 1:1 ratio of calcium (35% of the RDI) to phosphorus (30% of the RDI) per single serving. Such high levels of calcium and phosphorus are achieved without compromising physical stability (destabilization of protein) by using a soy protein in which the calcium is bound to the protein (insoluble calcium) in combination with other sources of insoluble calcium. The preferred soy protein source contains calcium in a colloidal suspension with the protein. U.S. Pat. No. 4,642,238 by H. C. Santz, et al., teaches how to produce a mineral enriched protein by combining a hydrated gel of an alkaline earth salt with soy protein isolate to form a mineral enriched soy protein composition. Preferably, about 85% of the total calcium is contributed by calcium bound to

soy protein and about 14% of total calcium is supplied by calcium citrate (insoluble calcium). Soluble calcium levels of more than about 0.1% (100 ppm or more) destabilizes the proteins during terminal sterilization.

Suspension of insoluble minerals, product stability and mouth feel is further improved by using one or more stabilizers. Useful stabilizers include, but are not limited to, cellulose gel and carrageenans. The stabilizer system comprises from about 1,000 to about 5,000 ppm cellulose gel, more preferably from about 1,500 to about 2,500 ppm cellulose gel and from about 100 to about 600 ppm carrageenan, more preferably from about 150 to about 300 ppm carrageenan. This combination of stabilizers will result in a viscosity ranging from about 10 to about 100 centipoise (cps), more preferably from about 20 to about 45 cps..

The nutritional products of the present invention will also desirably include a flavoring and or color to provide the nutritional products with an appealing appearance and an acceptable taste for oral consumption. The flavor systems cover or work with the heavy/nutty/bitter notes apparent in soy protein. Useful flavorings include, for example, strawberry, butter pecan, chocolate, banana and vanilla.

The nutritional products of this invention can be manufactured using techniques well known to those skilled in the art. While manufacturing variations are certainly well known to those skilled in the nutritional formulation arts, a few of the manufacturing techniques are described in detail in the Examples. Generally speaking an oil blend is prepared containing all oils, any emulsifier, and the fat soluble vitamins. Two more slurries (carbohydrate and protein) are prepared separately by mixing the carbohydrate and minerals together and the protein in water. The two slurries are then mixed together with the oil blend. The resulting mixture is homogenized, heat processed, standardized with water soluble vitamins, flavored and the liquid terminally sterilized or dried to produce a powder. The formula can be sterilized and subsequently utilized on a ready-to-feed (RTF) basis or stored in a concentrated liquid or a powder form.

EXAMPLE 1

Table 3 presents a bill of materials for manufacturing 454 kg (1,000 lbs.) of a vanilla flavored liquid nutritional product with soy protein containing standard or high genistein levels according to the present invention. A detailed description of its manufacture follows.

TABLE 3

Bill of Materials For Liquid Vanilla Flavored Product with Standard or High Genistein Soy Protein Isolate		
Ingredient Name	Standard Genistein	High Genistein
Water	347 kg (765 lbs)	340 kg (749 lbs)
Maltodextrin	35.6 kg (78.5 lbs)	15 kg (33.8 lbs)
Corn Syrup	NAP	29 kg (64.9 lbs)
Sucrose	32.2 kg (70.9 lbs)	28 kg (62.2 lbs)
Soy Protein Isolate	28 kg (61.7 lbs)	27.5 kg (60.7 lbs)
High Oleic Safflower Oil	1.76 kg (3.87 lbs)	
Canola Oil	1.76 kg (3.87 lbs)	
Potassium Citrate	1.77 lbs (3.90 lbs)	
Magnesium Phosphate	1.27 kg (2.80 lbs)	
Vanilla Flavor	0.91 kg (2.00 lbs)	
Cellulose Gel	0.91 kg (2.00 lbs)	
Corn Oil	0.88 kg (1.94 lbs)	
Calcium Citrate	0.45 kg (1.00 lbs)	
Choline Chloride	240 gm (0.529 lbs)	
Sodium Citrate	227 gm (0.500 lbs)	
Soy Lecithin	197 gm (0.435 lbs)	

TABLE 3-continued

Bill of Materials For Liquid Vanilla Flavored Product with Standard or High Genistein Soy Protein Isolate		
Ingredient Name	Standard Genistein	High Genistein
UTM/TM Premix*	163 gm (0.359 lbs)	
Ascorbic Acid	148 gm (0.326 lbs)	
Carrageenan	68 gm (0.150 lbs)	
Vitamin DEK premix**	44 gm (0.0970 lbs)	
WSV Premix	29 gm (0.0639 lbs)	
30% Beta Carotene	3.7 gm (0.00816 lbs)	
Vitamin A Palmitate Premix	1.6 gm (0.00364 lbs)	
Potassium Iodide	233 mg (0.000515 lbs)	
*The ultratrace mineral/trace mineral (UTM/TM) premix contributes 20.5 gm zinc sulfate (0.04504 lbs.), 26.6 gm ferrous sulfate (0.05858 lbs.), 7.6 gm manganese sulfate (0.01665.), 4.0 gm cupric sulfate (0.00864 lbs.), 250 mg chromium chloride (0.00055 lbs.), 200 mg sodium molybdate (0.00044 lbs.), 91 mg sodium selenate (0.00020 lbs.) to the product.		
**The vitamin D, E, K premix provides 6.3 mg vitamin D ₃ (0.000014 lbs.), 29.5 gm vitamin E (alphatocopherol acetate)(0.065090 lbs.), and 49 mg vitamin K (phyloquinone)(0.000108 lbs) to the product.		
The water soluble vitamin (WSV) premix provides 16.5 gm nicotinamide (0.03640 lbs.), 10.7 gm d-calcium pantothenate (0.02354 lbs.), 368 mg folic acid (0.00081 lbs.), 2.7 gm thiamine chloride HCl (0.00601 lbs.), 2.1 gm riboflavin (0.00469 lbs.), 2.6 gm pyroxidine HCl (0.00578 lbs.), 7.3 gm cyanocobalamin (0.000016 lbs.) and 322 mg biotin (0.00071 lbs.) to the product.		
Vitamin A palmitate premix provides 909 mg vitamin A palmitate (0.002002 lbs.) to the product.		

The liquid nutritional products of the present invention are manufactured by preparing three slurries which are blended together, heat treated, standardized, packaged and sterilized. The process for manufacturing 1,000 lbs. of a liquid nutritional product, using the bill of materials from Table 3, is described in detail below.

A carbohydrate/mineral slurry is prepared by combining the specified amount of cellulose gel (AviceL CL-611 distributed by FMC Corp., Philadelphia, Pa.) with the required amount of water under high agitation. The mixture is heated to a temperature of from about 140° F. to about 150° F. with agitation. The cellulose gel must be dissolved before the mineral addition. The following minerals are then added in the order listed, under high agitation: potassium citrate, sodium citrate, and UTM/TM premix (U.S. Pat. No. 5,221, 545 by M. W. Borschel, et al., teaches how to produce the premix used in this invention). The slurry is held under agitation for a minimum of 5 minutes. The remaining minerals are added, in the order listed under high agitation: potassium iodide, and magnesium phosphate. Next, the maltodextrin (Lodex 15 distributed by American Maize, Hammond, Ind.) is added to the slurry under high agitation, and is allowed to dissolve. The sugar (sucrose) is then added under high agitation and allowed to dissolve. The completed carbohydrate/mineral slurry is held under high agitation at a temperature from about 140° F. to about 150° F. for not longer than twelve hours until it is blended with the other slurries.

An oil blend is prepared by combining and heating the high oleic safflower oil, corn and canola oil to a temperature from about 130° F. to about 140° F. with agitation. An emulsifier (soy lecithin) is then added under agitation and allowed to dissolve. The Vitamin D,E,K premix (distributed by Vitamin, Inc., Chicago, Ill.), Vitamin A Palmitate, and 30% beta-carotene are then added to the slurry with agitation. A stabilizer (carrageenan Viscarin SD-389® distributed by FMC Corp., Philadelphia, Pa.) is added to the slurry with agitation and allowed to disperse. The completed oil slurry is held under moderate agitation at a temperature from about

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130° F. to about 140° F. for a period of no longer than twelve hours until it is blended with the other slurries.

A 10 to 12% protein-in-water slurry is prepared by first adding the soy protein isolate (Soy protein FXP-E-0101 distributed by Protein Technologies International, St. Louis, Mo.) to the required amount of water under high agitation. The slurry is heated to a temperature from about 85° F. to about 95° F. with agitation and held for a minimum of 15 minutes. The slurry temperature is then increased to a temperature of about 115° F. to about 125° F. and held for a minimum of 5 minutes. The slurry temperature is then increased to a temperature of about 145° F. to about 155° F. Cocoa powder (8 lbs.) is dispersed in the protein slurry for a chocolate flavored product. The completed protein-in-water slurry is held under moderate agitation at a temperature from about 145° F. to about 155° F. for a period of no longer than two hours until it is blended with the other slurries.

The protein-in-water and oil slurries are blended together with agitation and the resultant blend is maintained at a temperature from about 140° F. to about 150° F. After waiting for at least five minutes, the carbohydrate/mineral slurry is added to the blend from the preceding step with agitation and the resultant blend is maintained at a temperature from about 140° F. to about 150° F. The total solids of the final blend is about 25%. The blend pH is brought up to about 6.8 to about 7.0 with 1N KOH.

After waiting for a period of not less than five minutes nor greater than two hours, the blend is subjected to deaeration, ultra-high-temperature treatment, and homogenization, as follows:

- A. deaerate the blend at 10–15 in. Hg;
- B. preheat the blend through a plate/coil heat exchanger to 155–165° F.;
- C. emulsify the blend at 900–1100 psig;
- D. pass the blend through a plate/coil heater and heat the mix to from about 250° F. to about 255° F.;
- E. ultra high temperature heat the blend to a temperature of about 298° F. to about 302° F. with a hold time of about 5 seconds;
- F. reduce the temperature of the blend to from about 250° F. to about 255° F. by passing it through a flash cooler;
- G. reduce the temperature of the blend to from about 160° F. to about 170° F. by passing it through a plate/coil heat exchanger;
- H. homogenize the blend at about 3900 to about 4100 / about 400 to about 600 psig;
- I. pass the blend through a hold tube for at least 16 seconds at temperature from about 165° F. to about 175° F.;
- K. cool the blend to a temperature from about 34° F. to about 45° F. by passing it through a heat exchanger; and
- L. store the blend at a temperature from about 34° F. to about 45° F. with agitation.

After the above steps have been completed, appropriate analytical testing for quality control is conducted. Based on the analytical results of the quality control tests, an appropriate amount of water is added to the batch with agitation for dilution to about 22% total solids.

A vitamin solution and a flavor solution are prepared separately and added to the processed blend.

The vitamin solution is prepared by adding the following ingredients to the required amount of water, under agitation: Ascorbic Acid, Water Soluble Vitamin Premix (distributed by Fortitech, Inc., Schenectady, N.Y.) and Choline Chloride. The vitamin solution pH is adjusted to from about 6 to about 10 with 45% KOH. The vitamin slurry is then added to the blended slurry under agitation.

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The flavor solution is prepared by adding the natural and artificial flavor to the appropriate amount of water with agitation. The flavor slurry is then added to the blended slurry under agitation.

The product pH is adjusted to achieve optimal product stability. The completed product is then placed in suitable containers and subjected to terminal sterilization.

The final product total isoflavone content was 1.24 mg isoflavones / gm protein, 15.5 mg of isoflavones per 8 fl. oz serving. The genistein content was 0.86 mg genistein / gm protein, 10.7 mg of genistein per 8 fl. oz serving.

EXAMPLE II

Many studies have shown that daily consumption of at least 25 grams of soy protein are needed to maximize health promotion and wellness benefits. Twenty-five grams of standard soy proteins contains about 0.5 to 0.9 mg genistein per gram of protein. The use of soy protein containing high genistein would supply more isoflavones per unit weight of protein and consequently require less servings per day of the nutritional formula to meet the target.

Table 3 presents a bill of materials for manufacturing 454 kgm (1,000 Lbs) of a vanilla flavored liquid nutritional product with soy protein isolate containing high amounts of genistein according to the present invention.

The process for manufacturing 454 kgm (1,000 lbs.) of a liquid nutritional product, using the bill of materials for the high genistein product from Table 3, is described below.

A carbohydrate/mineral slurry is prepared as in Example 1 with a corn syrup addition prior to the maltodextrin addition. The corn syrup is added to slurry under high agitation and is allowed to dissolve. The completed carbohydrate/mineral slurry is held with high agitation at a temperature from about 140° F. to about 150° F. for not longer than twelve hours until it is blended with the other slurries.

The oil slurry is prepared as in Example 1 and is held under moderate agitation at a temperature from about 130° F. to about 140° F. for a period of no longer than twelve hours until it is blended with the other slurries.

A 10% to 12% protein-in-water slurry is prepared as in Example I. The product is manufactured using soy protein isolate distributed by PTI, St. Louis, Mo., under the trade designation "Soy Protein Isolate FXP-H01 18." The completed protein-in-water slurry is held under moderate agitation at a temperature from about 145° F. to about 155° F. for a period of no longer than two hours until it is blended with the other slurries.

The protein-in-water, oil and carbohydrate/mineral slurries are blended together and pH adjusted as in Example I.

After waiting for a period of not less than five minutes nor greater than two hours, the blend is subjected to deaeration, ultra-high-temperature treatment, and homogenization as described in Example I.

As described in Example I the water soluble vitamin and flavor solutions are added and final product pH adjusted to achieve optimal product stability. The completed product is then placed in suitable containers and subjected to terminal sterilization.

The final product total isoflavone content was 1.52 mg isoflavones / gm protein, 19 mg of isoflavones per 8 fl. oz serving. The genistein content was 0.99 mg genistein / gm protein, 12.4 mg of genistein per 8 fl. oz serving.

EXAMPLE III

In order to decrease costs and increase shelf life, a powder form of the liquid nutritional would be beneficial.

Table 4 presents a bill of materials for manufacturing 454 kg (1,000 Lbs) of a vanilla flavored spray dried powder nutritional product according to the present invention. A detailed description of its manufacture follows.

TABLE 4

Bill of Materials for Spray Dried Powder Vanilla Flavored Product with Standard Genistein Soy Protein Isolate	
Ingredient Name	Powder Product
Corn Syrup	99.6 kg (219.4 lbs)
Sucrose	122 kg (269.5 lbs)
Soy Protein Isolate	117.6 kg (259.0 lbs)
Maltodextrin	66.6 kg (146.7 lbs)
High Oleic Safflower Oil	8.2 kg (18.1 lbs)
Canola Oil	8.2 kg (18.1 lbs)
Potassium Citrate	3.5 kg (7.7 lbs)
Magnesium Phosphate	5.0 kg (11.2 lbs)
Vanilla Flavor	4.6 kg (10.2 lbs)
Corn Oil	4.1 kg (9.0 lbs)
Choline Chloride	0.99 kg (2.2 lbs)
Sodium Citrate	3.5 kg (7.7 lbs)
UTM/TM Premix*	0.7 kg (1.5 lbs)
Ascorbic Acid	0.65 kg (1.4 lbs)
mixed tocopherols	22.7 gm (0.05 lbs)
Vitamin DEK premix**	0.19 kg (0.4 lbs)
WSV Premix	0.12 kg (0.27 lbs)
Vitamin A Palmitate	72.6 gm (0.02 lbs)
Potassium Iodide	458.5 mg (0.001 lbs)

*The ultratrace mineral/trace mineral (UTM/TM) premix provides 88 gm zinc sulfate (0.194077 lbs.), 114 gm encapsulated ferrous sulfate (0.251651 lbs.), 32 gm manganese sulfate (0.071775 lbs.), 17 gm cupric sulfate (0.037023 lbs.), 1 gm chromium chloride (0.002380 lbs.), 1 gm sodium molybdate (0.002380 lbs.), 387 mcg sodium selenate (0.000854 lbs.) to the product.

**The vitamin D, E, K premix provides 27 mcg vitamin D (0.000061 lbs.), 127 gm vitamin E (0.279874 lbs.), and 212 mcg vitamin K (0.000468 lbs) to the product.

The water soluble vitamin (WSV) premix provides 47 gm niacinamide (0.103155 lbs.), 30 gm d-calcium pantothenate (0.066724 lbs.), 1 gm folic acid (0.002311 lbs.), 8 gm thiamine chloride HCl (0.017030 lbs.), 6 gm riboflavin (0.013309 lbs.), 7 gm pyroxidine HCl (0.016392 lbs.), 20 mcg cyanocobalamin (0.000046 lbs.) and 911 mcg biotin (0.002008 lbs.) to the product.

Vitamin A palmitate premix provides 4 gm vitamin A palmitate (0.008608 lbs.) to the product.

The powder nutritional products of the present invention are manufactured by preparing three slurries which are blended together, heat treated, standardized, spray dried, (and dry blended as in Example IV) and packaged. The process for manufacturing 1,000 lbs. of a spray dried powder nutritional product, using the bill of materials from Table 4, is described in detail below.

A 45% to about 55% total solids carbohydrate/mineral slurry is prepared by heating the required amount of water to about 145° F. to about 150° F. The following minerals are added in the order listed, under high agitation: potassium citrate, sodium citrate, and UTM/TM premix (distributed by Fortitech, Inc., Schenectady, N.Y.). The slurry is held under agitation for a minimum of 5 minutes. The remaining minerals are added in the order listed under high agitation: potassium iodide, and magnesium phosphate. The corn syrup is added under high agitation and allowed to dissolve. Next, the maltodextrin (Maltrin 40 distributed by Grain Processing Corporation, Muscatine, Iowa) is added to slurry under high agitation, and is allowed to dissolve. The sugar (sucrose) is then added under high agitation and allowed to dissolve. The completed carbohydrate/mineral slurry is held with high agitation at a temperature from about 140° F. to about 150° F. for not longer than twelve hours until it is blended with the other slurries.

The oil slurry is prepared by combining and heating the high oleic safflower oil, corn and canola oil to a temperature from about 130° F. to about 140° F. with agitation. The

Vitamin D,E,K premix (distributed by Vitamins, Inc., Chicago, Ill.), Vitamin A Palmitate and mixed tocopherols (Tenox GT distributed by Eastman Chemical Company, Kingsport, Tn.) are then added to the slurry with agitation. The completed oil slurry is held under moderate agitation at a temperature from about 130° F. to about 140° F. for a period of no longer than twelve hours until it was blended with the other slurries.

A 18% to about 22% total solids protein-in-water slurry is prepared by first dispersing the soy protein isolate (Supro Plus 675 distributed by Protein Technologies International, St. Louis, Mo.) in the required amount of water under high agitation. The completed protein-in-water slurry is held under moderate agitation at a temperature from about 145° F. to about 155° F. for a period of no longer than two hours until it is blended with the other slurries.

The protein-in-water and oil slurries are blended together with agitation and the resultant blend is maintained at a temperature from about 140° F. to about 150° F. After waiting for at least five minutes, the carbohydrate/mineral slurry is added to the blend from the preceding step with agitation and the resultant blend is maintained at a temperature from about 140° F. to about 150° F. The total solids of the final blend is about 40% to about 44%. The blend pH is brought up to about 6.8 to about 7.0 with 1N KOH.

After waiting for a period of not less than five minutes nor greater than two hours, the blend is subjected to deaeration, HTST treatment, and homogenization, as follows:

- a. deaerate the blend at 10–15 in. Hg;
- b. preheat the blend through a plate/coil heat exchanger to 155–165F;
- c. emulsify the blend at 900–1100 psig;
- d. heat the blend to a temperature from about 160F. to about 170F. by passing it through a plate/coil heat exchanger, pass the blend through a hold tube for at least 16 seconds at temperature from about 160F. to about 170F;
- e. homogenize the blend at about 3900 to about 4100/ about 400 to about 600 psig;
- f. cool the blend to a temperature from about 34F. to about 45F. by passing it through a heat exchanger; and
- g. store the blend at a temperature from about 34F. to about 45F. with agitation.

After the above steps have been completed, appropriate analytical testing for quality control is conducted. A vitamin solution and a flavor solution are prepared separately and added to the processed blend.

The vitamin solution is prepared by adding the following ingredients to the required amount of water, under agitation: Ascorbic Acid, Water Soluble Vitamin Premix (distributed by Fortitech, Inc., Schenectady, N.Y.) and Choline Chloride. The vitamin solution pH is adjusted to from about 6 to about 10 with 45% KOH. The vitamin slurry is then added to the blended slurry under agitation.

The flavor solution is prepared by adding the natural and artificial flavor to a minimal amount of water with agitation. The flavor slurry is then added to the blended slurry under agitation.

The total solids of the final standardized product is 40%. The product is preheated to 165° F. and homogenized at about 2500/500 psig before spray drying. A pilot scale high pressure nozzle tower spray drier (distributed by NIRO Hudson Inc., Hudson, Wisc.) is used to dry the product. Drying conditions are an inlet temperature of 380° F. with an outlet temperature of 218° F. and nozzle #24 is used. The resulting powder is packaged under nitrogen to maximize product stability and flavor.

The final product total isoflavone content was 1.2 mg isoflavones / gm protein, 15 gm isoflavones per 8 fl. oz

serving. The genistein content was 0.8 mg genistein / gm protein, 10 mg isoflavones per 8 fl. oz serving.

EXAMPLE IV

A less expensive process of manufacturing a powder is to dry blend major carbohydrates, proteins and powder flavor components into a spray dried base. The powder nutritional products of the present invention are also manufactured in a two-step spray dry/dry blend process. The spray dried base contains 100% of the oil blend, minerals, water soluble vitamins and oil soluble vitamins, 7% of the protein and 7% of the carbohydrates. The spray dried base is made by blending three slurries together, heat treating, standardizing, and spray drying as in Example III. The spray dried base is dry blended with the remaining carbohydrate, protein, flavor and ultratrace mineral/trace mineral premix. The process for manufacturing 1,000 lbs. of a powder nutritional product, using the bill of materials from Table 5, is described below.

TABLE 5

Bill of Materials for Dry Blended Powder Vanilla Flavored Product with Standard Genistein Soy Protein Isolate	
Ingredient Name	
	<u>Spray Dry Base</u>
Soy Protein Isolate	8.5 kg (18.7 lbs)
Maltodextrin	20 kg (43.8 lbs)
High Oleic Safflower Oil	8.2 kg (18.1 lbs)
Canola Oil	8.2kg (18.1 lbs)
Potassium Citrate	3.5 kg (7.7 lbs)
Magnesium Phosphate	5.0 kg (11.2 lbs)
Vanilla Flavor	4.6 kg (10.2 lbs)
Corn Oil	4.1 kg (9.0 lbs)
Choline Chloride	0.99 kg (2.2 lbs)
Sodium Citrate	3.5 kg (7.7 lbs)
Ascorbic Acid	0.65 kg (1.4 lbs)
mixed tocopherols	22.7 gm (0.05 lbs)
Vitamin DEK premix**	0.19 kg (0.4 lbs)
WSV Premix	0.12 kg (0.27 lbs)
Vitamin A Palmitate	72.6 gm (0.02 lbs)
Potassium Iodide	458.5 mg (0.001 lbs)
	<u>Dry Blend Ingredients</u>
Spray Dried Base	All
Sucrose	138 kg (300 lbs)
Soy Protein Isolate	110 kg (242 lbs)
Maltodextrin	137 kg (302 lbs)
UTM/TM Premix*	0.7 kg (1.5 lbs)

*The ultratrace mineral/trace mineral (UTM/TM) premix provides 88 gm zinc sulfate (0.194077 lbs.), 114 gm encapsulated ferrous sulfate (0.251651 lbs.), 32 gm manganese sulfate (0.071775 lbs.), 17 gm cupric sulfate (0.037023 lbs.), 1 gm chromium chloride (0.002380 lbs.), 1 gm sodium molybdate (0.002380 lbs), 387 mcg sodium selenate (0.000854 lbs.) to the product.

**The vitamin D, E, K premix provides 27 mcg vitamin D (0.000061 lbs.), 127 gm vitamin E (0.279874 lbs.), and 212 mcg vitamin K (0.000468 lbs) to the product.

The water soluble vitamin (WSV) premix provides 47 gm niacinamide (0.103155 lbs.), 30 gm d-calcium pantothenate (0.066724 lbs.), 1 gm folic acid (0.002311 lbs.), 8 gm thiamine chloride HCl (0.017030 lbs.), 6 gm riboflavin (0.013309 lbs.), 7 gm pyroxidine HCl (0.016392 lbs.), 20 mcg cyanocobalamin (0.000046 lbs.) and 911 mcg biotin (0.002008 lbs.) to the product.

Vitamin A palmitate premix provides 4 gm vitamin A palmitate (0.008608 lbs.) to the product.

The carbohydrate slurry is prepared as described in Example III using the amount of maltodextrin (Maltin 40 distributed by Grain Processing Covoration, Muscataine, Iowa) listed in Table 5. The slurry is held with high agitation at a temperature from about 140° F. to about 150° F. for not longer than twelve hours until it is blended with the other slurries.

The oil slurry is prepared as described in Example III and is held under moderate agitation at a temperature from about

130° F. to about 140° F. for a period of no longer than twelve hours until it is blended with the other slurries.

A protein-in-water slurry is prepared as described in Example III using the amount of soy protein isolate (Supro Plus 675 distributed by PTI, St. Louis, Mo.) listed in Table 5. The completed protein-in-water slurry is held under moderate agitation at a temperature from about 145° F. to about 155° F. for a period of no longer than two hours until it is blended with the other slurries.

The protein-in-water, oil and carbohydrate/mineral slurries are blended together and the pH adjusted as described in Example III.

After waiting for a period of not less than five minutes nor greater than two hours, the blend is subjected to deaeration, HTST treatment, and homogenization as described in Example III.

A vitamin solution is prepared separately and added to the processed blend as in Example III.

The above mixture is spray dried as in Example III. The resulting spray dried base is dry blended with the remaining ingredients listed on Table 5. This two step process of spray drying a base and dry blending in the remaining ingredients is well known to those skilled in the art. U.S. Pat. No. 5,587,399 by P. J. Acosta, et al., teaches a method of preparing a nutritional product in which a powder base containing fats, carbohydrates, vitamins, mineral and trace elements is dry blended with specific amino acids to yield several different therapeutic products. This patent is incorporated herein by reference.

The embodiments of the present invention may, of course, be carried out in other ways than those set forth herein without departing from the spirit and scope of the invention. The present embodiments are, therefore, to be considered in all respects as illustrative.

We claim:

1. A stable calcium enriched soy-based nutritional product comprising:

- (a) an isoflavone enriched soy protein source;
- (b) a calcium source providing 35% of the RDI for calcium;
- (c) a soluble calcium source at a level no greater than about 100 ppm; and
- (d) a stabilizer system wherein said stabilizer system is a mixture of cellulose gel and carrageenan.

2. The calcium enriched soy-based nutritional product of claim 1 wherein said calcium source further comprises soy protein with bound calcium and calcium citrate.

3. The calcium enriched soy-based nutritional product of claim 1 wherein said stabilizer system comprises from about 1500 to about 2500 ppm cellulose gel and from about 150 to about 300 ppm carrageenan.

4. A stable terminally sterilized calcium enriched soy-based liquid nutritional product comprising:

- (a) an isoflavone enriched soy protein source;
 - (b) a carbohydrate system wherein said carbohydrate system contains at least corn syrup and maltodextrin;
 - (c) one or more sources of calcium providing a total of at least about 35% of the RDI for calcium in about 8 fl. oz.; and
- said nutritional contains at most about 100 ppm of soluble calcium.

5. The stable terminally sterilized soy-based liquid nutritional product of claim 4 wherein said carbohydrate system comprises from about 35% to 52% of total carbohydrate as corn syrup, from 0 to about 22% of total carbohydrate as maltodextrin and from about 43% to 48% of total carbohydrate as sucrose.

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6. A method for providing soy protein to an individual comprising enterally feeding the stable calcium enriched soy-based nutritional product according to claim 1.

7. A method for providing isoflavones to an individual comprising enterally feeding said individual the stable calcium enriched soy-based nutritional product according to claim 1.

8. A method for providing calcium to an individual comprising enterally feeding said individual the stable calcium enriched soy-based nutritional product according to claim 1.

9. A stable calcium enriched soy-based nutritional product comprising:

- (a) an isoflavone enriched soy protein source supplying from about 17% to about 25% of the total calories of the product;
- (b) a lipid source supplying from about 5% to about 15% of the total calories of the product;
- (c) a source of carbohydrate supplying from about 56% to about 68% of the total calories of the product;
- (d) one or more sources of calcium providing a total of at least about 35% of the RDI for calcium in about 8 fl. oz.; and

said nutritional contains at most about 100 ppm of soluble calcium.

10. The stable calcium enriched soy-based nutritional product according to claim 9 in which the isoflavone enriched soy protein source comprises at least 0.7 mg isoflavones / gm soy protein.

11. The stable calcium enriched soy-based nutritional product according to claim 9 in which the isoflavone enriched soy protein source comprises at least 0.5 mg genistein / gm soy protein.

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12. The stable calcium enriched soy-based nutritional product according to claim 9 wherein the lipid source supplies from about 10% to about 14% of the total calories of the product.

13. The stable calcium enriched soy-based nutritional product according to claim 9 wherein the carbohydrate source supplies from about 57% to about 65% of the total calories of the product.

14. The stable calcium enriched soy-based nutritional product according to claim 13 in which the carbohydrate source contains a blend at least corn syrup and maltodextrin.

15. The stable calcium enriched soy-based nutritional product of claim 9 wherein the vitamin and mineral system further comprises Vitamin A, beta-carotene, Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D, Vitamin E, Vitamin K, Biotin, Folic Acid, Pantothenic Acid, Niacin, Choline, potassium, sodium, phosphorous, magnesium, chloride, trace minerals, and ultra trace minerals.

16. The stable calcium enriched soy-based nutritional product according to claims 9 wherein the caloric density is from about 0.60 kcal/ml to about 1.10 kcal/ml.

17. A method for providing soy protein to an individual comprising enterally feeding the stable calcium enriched soy-based nutritional product according to claim 9.

18. A method for providing isoflavones to an individual comprising enterally feeding said individual the stable calcium enriched soy-based nutritional product according to claim 10.

19. A method for providing genistein to an individual comprising enterally feeding said individual the stable calcium enriched soy-based nutritional product according to claim 11.

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ANEXO 2



US006096343A

United States Patent [19]
Gergely et al.

[11] **Patent Number:** **6,096,343**
[45] **Date of Patent:** **Aug. 1, 2000**

[54] **INSTANT CALCIUM/SOYBEAN GRANULES, THEIR USE AND PROCESS FOR THEIR PREPARATION**

5,487,894 1/1996 Kovacs 424/195.1
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5,654,011 8/1997 Jackson et al. 424/635

[75] Inventors: **Gerhard Gergely**, Gartengasse 8, A-1053 Vienna; **Irmgard Gergely**, Vienna; **Thomas Gergely**, Vienna; **Stefan Gergely**, Vienna, all of Austria

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[73] Assignee: **Gerhard Gergely**, Vienna, Australia

[21] Appl. No.: **09/179,391**

Primary Examiner—Thurman K. Page
Assistant Examiner—Alysia Berman
Attorney, Agent, or Firm—Oliff & Berridge, PLC

[22] Filed: **Oct. 27, 1998**

Related U.S. Application Data

[60] Provisional application No. 60/063,674, Oct. 29, 1997.

Foreign Application Priority Data

Oct. 29, 1997 [CH] Switzerland 2505/97

[51] **Int. Cl.⁷** **A61K 9/16; A01N 65/00**

[52] **U.S. Cl.** **424/499; 424/195.1**

[58] **Field of Search** 424/195.1, 499; 514/456

[57] **ABSTRACT**

The invention relates to instant granules which contain at least one isoflavone-containing soybean material, at least one calcium compound and optionally vitamin D3 or other additives in granules in which the particles of soybean material and the calcium compound are present intimately mixed and bound to one another preferably with the aid of a binder—optionally with the addition of a surfactant.

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,424,331 6/1995 Shlyankevich 514/456

The invention furthermore relates to a process for the preparation of the instant granules and to their use.

17 Claims, No Drawings

6,096,343

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INSTANT CALCIUM/SOYBEAN GRANULES, THEIR USE AND PROCESS FOR THEIR PREPARATION

This nonprovisional application claims the benefit of U.S. Provisional Application No. 60/063,674, filed Oct. 29, 1997.

The invention relates to instant granules according to the preamble of claim 1, a process for their preparation, and the use of a mixture of at least one soybean material with at least one pharmaceutically permissible calcium compound.

EP-A2 398 867 describes a cocoa-containing drink for children and young persons in the growth phase which has a high nutritional value and, in addition to cocoa, also contains sweeteners, flavors, wheatgerms, soybean protein, calcium and magnesium, the vitamins B1, B2, B6 and C and lecithin as emulsifier. Lactose may be added to promote calcium absorption but is physiologically undesirable, particularly in the proposed amounts.

On the other hand, instant granules according to the defining features of claim 1, which, owing to their high dose of calcium ions and of the essential ingredients of soybean, namely the isoflavones, could not to date be brought into a form capable of oral administration, are proposed according to the invention. Furthermore, the use of vitamin D3 or of sodium monofluorophosphate (in contrast to the EP-A1 mentioned at the outset and to conventional calcium-containing tablets) for improving the calcium absorption, and the use of such granules for the treatment and prevention of osteoporosis, are proposed according to the invention.

Suitable isoflavone donors are in particular concentrated soybean isoflavones from CentralSoya® (U.S.A) containing 5% of isoflavones or those from NovaSoy® (U.S.A) containing 40% of isoflavones.

Soybean products have for some time been known as effective components in the prevention of osteoporosis (Journal of Nutrition, March 1995). Various studies have backed up this assumption; the eating habits in Asiatic countries compared with those of Western countries have shown a relationship to the occurrence of osteoporosis.

In Western countries, osteoporosis is treated by various measures, in particular with high doses of calcium in combination with vitamin D3. There is now a large number of scientific publications in which, owing to their content of phytoestrogens, soybean protein powders play an important role in the prevention of menopausal symptoms and osteoporosis (Annual Review of Nutrition 1997). Owing to their estrogen activity, they can to a certain degree prevent osteoporosis. A report of the Royal Hospital for Women in Australia reveals that, owing to their high phytoestrogen content, soybean products have an advantageous effect in the treatment of osteoporosis. A further study states that soybean proteins can be effectively used for preventing atrophy of the bone due to hormone deficiency.

Regarding the prior art: It is known (publication "Bone mash calcium supplementing paste") that calcium and a soybean material can be administered in a paste. This is a pasty material which contains predominantly powdered pig and cattle bones and contains only 2-3% of soybean powder, but no indication of a solution to the problem of instant granules containing calcium and soybean [sic].

The object of the invention was to develop a product to bring the desired soybean material in powder form together with calcium compounds and optionally vitamins, in particular vitamin D3, fluorine compounds and/or amino acids into the pharmaceutical form of instant granules which contain a considerable amount of soybean material together

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with organic and/or inorganic calcium-containing substances and, on dissolution, can be suspended in a glass of water.

In the preparation of instant granules, the problem of granulation of the soybean material and the achievement of good wettability of the granules had to be solved. Another problem was to suspend both the calcium compounds and the soybean material so that it was possible to obtain a suspension which was stable—for at least 5 minutes—without sedimentation.

According to the invention, it is now possible to produce instant calcium/soybean granules for the preparation of both pH-neutral drinks and acid-containing drinks, the common feature of which granules is that the poorly wettable soybean powders are granulated with surfactant substances together with calcium compounds to give a readily suspendable drink in which both the consumption of soybean material and the consumption of the calcium compound are associated with one another in a pleasant and expedient manner.

The object was for a dose to contain about 500 to 1200 mg of calcium ions and also 0.1 to 10 g of soybean material, and in addition to this vitamin D3, preferably in an amount of 100 to 1000, in particular 200 to 800, IU, or fluorine compounds, for example in an amount of 50 to 100 mg of sodium monofluorophosphate, may be incorporated for the prevention or therapy of osteoporosis.

Suitable soybean materials are both defatted and fat-containing soybean flours, defatted soybean flours being preferred, and furthermore soybean protein powder, pulverized soybean meal (full-fat or defatted) or mixtures of these products.

However, soybean material which is rich in the two most important isoflavones, genistein and daidzein, is preferred. Based on the consumption of soybean products in Japan, a typical daily dose of isoflavones is about 50 mg per person (according to American Journal of Chemical Nutrition 1995). In the case of soybean material which is rich in isoflavones and contains, for example, 40% of isoflavones, only a dose of, for example, about 125 mg of soybean material is required, i.e. there is no longer any need to administer large amounts of soybean flour. Furthermore, soybean isoflavone concentrates which contain all essential isoflavones, such as daidzeins, glyciteins and genisteins, are also commercially available. It is also possible to use commercial concentrated soybean proteins or soybean protein concentrates which contain the essential isoflavones—preferably in enriched form.

Suitable calcium carriers are mainly organic calcium compounds, such as, for example, calcium glycerophosphate, tricalcium dicitrate, monocalcium citrate, calcium levulinate, calcium malate and others.

Suitable inorganic calcium compounds are mainly calcium carbonate, calcium biphosphate, calcium chloride, calcium phosphate and others.

The choice of calcium compounds makes it possible to prepare a large number of drinks from acidic to neutral with a very wide range of flavours from fruity to creamy. Of course, the resulting granules may also be sweetened in a variety of ways with the permitted sweeteners, such as sodium cyclamate, saccharin Na, aspartame or acesulfame, and may be provided with flavors.

Furthermore, fillers for the formation of granules are used, such as maltodextrin (e.g. Maltrin M 700®), and/or sugar alcohols, such as sorbitol or mannitol; glucose, fructose, lactose, sucrose, corn starch and/or hydrolyzed starches may also be used.

As additives to the combination of soybean with calcium, it is also possible to integrate vitamins, for example the

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vitamins of the B complex, fat-soluble vitamins, such as A, D and E, and folic acid, biotin, cyanocobalamin, nicotinamide, calcium pantothenate and/or vitamin C, as well as trace elements, such as, for example, manganese, copper and zinc, and also minerals, such as potassium, magnesium, iron, etc. In addition, enrichment with lysine, myoinositol and further amino acids, for example arginine aspartate, valine, isoleucine, alanine, cystine, glutamic acid, glycine, phenylalanine, histidine, threonine, tyrosine, etc., is also possible.

The preparation of instant calcium/soybean granules having relatively high calcium doses is illustrated with reference to some examples, and an instant calcium/soybean product which also contains vitamins, minerals and trace elements and some amino acids in addition to calcium is also described.

The preparation is best carried out by moistening and granulating the calcium compound together with the fillers and the optionally added minerals and/or sweeteners with the solution of a binder and then applying the soybean powder to the moist granules and warming the material to 60° C. while stirring, the initial granulation of the soybean material taking place as a result of the moisture present. The binder solution contains, as a solvent, alcohol or a mixture of alcohol and water and, as an additive, a surfactant. The resulting product is then dried, vacuum drying being preferred; however, it is also possible to dry the granules in a fluidized-bed dryer. Drying gives free-flowing granules in whose grains the particles of the calcium compound(s) and of the pulverulent soybean material are present as an intimate mixture. To achieve a uniform particle size if required, the granules can be sieved, for example to a particle size of 1.5 to 2.5 mm, and packed in individual cans.

The binders which are required to granulate the two substances, i.e. the soybean flour and the calcium compound, should preferably be substances which are soluble in organic solvents or solvent mixtures with water. These include primarily polyvinylpyrrolidone, polyethylene glycol 6000 and also concentrated solutions of sugar alcohols. However, sucrose, fructose and glucose may also be used. As mentioned at the outset, alcohol-soluble substances or substances soluble in organic aqueous solvents are preferred because, on the one hand, granulation with purely aqueous binder solutions may adversely affect in particular the soybean protein powder with its active principles and because, on the other hand, drying of calcium/soybean granules treated with aqueous solution is possible only with difficulty.

Advantageously used surfactants which may be employed for better wettability of the various soybean powders or for improvement of the suspendability of calcium/soybean granules are sodium dioctylsulfosuccinate, polysorbates, polyoxyethylene glyceryl fatty acid esters, sodium laurylsulfate and the like.

The invention is to be illustrated with reference to some examples:

EXAMPLE 1

Preparation of calcium/soybean granules containing 500 mg of calcium and 400 IU of vitamin D3:

125 parts by weight of calcium carbonate, 25 parts by weight of sorbitol, 37 parts by weight of sucrose, 400 parts by weight of maltodextrin and 4 parts by weight of aspartame are uniformly mixed with heating and stirring. The mixture is wet with a solution consisting of 1.5 parts by weight of polysorbate, 16.8 parts by weight of liquid glucose syrup (equivalent to 13.5, based on solid) in 50 parts by weight of 40% ethanol and uniformly distributed for 3

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minutes. 770 parts by weight of soybean flour are added and the mixture is heated to 60–65° C. while stirring, granulation taking place. The product is then dried, both vacuum drying and belt drying being possible.

400 IU of vitamin D3 and flavors are added to the granules sieved to 1.5–2.0 mm. In addition to 500 mg of calcium ion and 400 IU of vitamin D3, a dose of 14 g furthermore contains 7.7 g of soybean flour, corresponding to a content of 15.4–23 mg of isoflavones (according to Technical Bulletin, 1 gram of soybean flour contains 2–3 mg of isoflavones). When introduced into water and stirred briefly, this gives a milky, pleasant-tasting suspension.

As mentioned in Example 1, instead of soybean flour it is also possible to process soybean proteins and soybean material enriched with isoflavones, the required amount of granulating solution being dependent to a certain degree on the soybean material used.

In the case of organic calcium salts, the calcium salts may also be mixed with soybean flour and then granulated with an alcoholic or alcoholic-aqueous solution containing a binder.

EXAMPLE 2

As an example of an acidic drink:

6 parts by weight of pulverulent soybean material are mixed with 5.75 parts by weight of monocalcium citrate, heated to 50° C. and granulated with a solution consisting of 0.02 part by weight of polyvinylpyrrolidone in 0.2 part by weight of ethanol. A dose of 11.8 g contains 1000 mg of calcium ions and 6 g of soybean product, corresponding to a content of 12–18 mg of isoflavones (or corresponding to a content of 25–40 mg of isoflavones when an enriched soybean material is used), and can be provided with fruit flavors, sweeteners and colors.

EXAMPLE 3

With calcium glycerophosphate as the calcium compound:

The preparation is carried out analogously to the preceding Examples. 10 parts by weight of pulverulent soybean material are mixed with 5.2 parts by weight of calcium glycerophosphate (corresponding to 1000 mg of calcium ion) in a granulator. The product is heated to 50° C. with mixing and is granulated with a solution consisting of 0.7 part by weight of ethanol, 1 part by weight of polyethylene glycol 6000, which is melted, and 0.004 part by weight of sorbitan oleate (Tween®). The product is dried with stirring, sieved through a sieve of 1 to 2 mm, preferably by means of a vacuum, and mixed with 0.7 part by weight of flavor and, if desired, with a corresponding amount of sweetener and optionally of color.

A dose of 16.2 g—corresponding to 1000 mg of calcium and 20–30 mg of isoflavones—gives a readily suspendable drink.

EXAMPLE 4

Preparation of calcium/soybean granules containing 160 mg of calcium and minerals (magnesium and iron), trace elements, vitamins and amino acids:

The following are introduced into a vacuum granulator: 688 parts by weight of calcium hydrogen phosphate, 44 parts by weight of potassium carbonate, 286 parts by weight of trimagnesium dicitrate, 21 parts by weight of iron gluconate, 625 parts by weight of lysine HCl, 12.5 parts by weight of myoinositol, 4000 parts by weight of maltodextrin, 60 parts by weight of aspartame, 200 parts by weight of citric acid and 363 parts by weight of sucrose are homogeneously mixed. A solution consisting of 15 parts by weight of polysorbate and 135 parts by weight of liquid glucose syrup

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dissolved in 490 parts by weight of 40% ethanol is applied to this mixture and uniformly distributed. 8300 parts by weight of soybean flour are added to this moistened mixture and the latter is heated to 60° C. with stirring, granulation taking place. The moist granules are dried at a temperature of 40–55° C. by means of a vacuum while stirring. A mixture of vitamins of the B complex, vitamin C and vitamin A, D and E, and furthermore trace elements, such as manganese, copper and zinc, and optionally further amino acids may be mixed with the granules which have been dried and sieved to the desired particle size. With orange and lemon flavors, a dose of 14–18 g (containing 8.3 g of soybean flour or 16.6–25 mg of isoflavones), the product gives a readily suspendable, pleasant-tasting drink.

To achieve optimum dissolution of the instant granules, according to the invention the soybean material (e.g. soybean flour) is preferably granulated either with a soluble organic calcium compound or with a mixture of a suitable filler and an insoluble inorganic calcium compound with the aid of a suitable binder, such as, for example, glucose syrup, which contains a wetting agent, such as, for example, polysorbate. In this way, it is ensured that the protein-containing soybean material (e.g. soybean flour) is thoroughly wet and does not form lumps and therefore also does not have the disadvantage that it is difficult to suspend in a drink. The filler or the soluble calcium compounds are in fact superficially dissolved, the soybean product is incorporated there and the instant granules can then be much more readily suspended. The addition of a polysorbate to a glucose syrup as granulating solution has proven very expedient.

What is claimed is:

1. A process for the preparation of instant granules that comprise at least one isoflavone-containing soybean material and at least one pharmaceutically permissible calcium compound, wherein the granules contain, per dose, 0.1 to 10 g of a soybean material containing 5 to 100 mg of isoflavones, 100 to 1200 mg of calcium ions and a binder, and wherein at least one pulverulent calcium compound is wetted with an organic or aqueous organic solution of a binder, after which at least one pulverulent, isoflavone-containing soybean material is applied, with stirring and heating, whereafter the resulting granules are dried and packed in single doses.

2. A process for the preparation of instant granules that comprise at least one isoflavone-containing soybean material and at least one pharmaceutically permissible calcium compound, wherein the granules contain, per dose, 0.1 to 10 g of a soybean material containing 5 to 100 mg of isoflavones and in addition 100 to 1200 mg of calcium ions and a binder, and wherein at least one organic calcium compound is initially taken together with at least one pulverulent, isoflavone-containing soybean material and optionally further additives, mixing is carried out, wetting is then effected with an organic or aqueous organic solution of a binder and granulation is carried out with stirring and

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heating, and the resulting granules are dried and packed in single doses.

3. The process as claimed in claim 1, wherein after wetting said calcium compound with said binder solution at least one compound selected from the group consisting of pharmaceutically acceptable fillers and additives is added.

4. The process as claimed in claim 2, wherein after wetting said calcium compound with said binder solution at least one compound selected from the group consisting of pharmaceutically acceptable fillers and additives is added.

5. The process as claimed in claim 1 or 2, wherein the isoflavone content is 10 to 50 mg per dose.

6. The process as claimed in claim 1 or 2, wherein the calcium compound is present in inorganic form as carbonate, chloride, phosphate, or hydrogen phosphate or in organic form as glycerophosphate, levulinate, malate or citrate and the calcium ion content is preferably 400 to 1000 mg per dose.

7. The process as claimed in claim 1 or 2, in which the granules furthermore contain, per dose, 100 to 1000 IU of vitamin D3 or 50 to 100 mg of sodium monofluorophosphate.

8. The process as claimed in claim 1 or 2, wherein the soybean material is pulverulent and particles of the soybean material are present as an intimate mixture with particles of the calcium compound in granules which preferably contain a binder and optionally also a surfactant.

9. The process as claimed in claim 1 or 2, wherein the binder is soluble in an organic or water-containing organic solvent.

10. The process as claimed in claim 1 or 2, wherein the calcium compound is present in inorganic form and in addition up to 40% by weight of at least one filler is present.

11. The process as claimed in claim 1 or 2, wherein at least one substance from the group consisting of the amino acids, vitamins, minerals and trace elements is added.

12. The process as claimed in claim 1 or 2, wherein the binder solution contains a surfactant.

13. The process as claimed in claim 1 or 2, wherein the dried granules are sieved to the desired particle size.

14. The process as claimed in claim 1 or 2, wherein each single dose comprises 200 to 800 IU of vitamin D3.

15. The process as claimed in claim 1 or 2, wherein said binder is selected from the group consisting of polyvinylpyrrolidone, polyethylene glycol 6000, and glucose syrup.

16. The process as claimed in claim 3 or 4, wherein said at least one compound is present in an amount of 5% to 35% by weight.

17. The process as claimed in claim 3 or 4, wherein said at least one compound is selected from the group consisting of maltodextrin, sugar alcohols, mono-saccharides, di-saccharides, vitamins, trace elements, and amino acids.

* * * * *



Industria y Comercio
SUPERINTENDENCIA

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO


No. 08-0110024-00006-0000

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Act. 400 OPOSIOBSERVTER Folios: 20

FORMULARIO UNICO DE OPOSICION
2000-12

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OPOSICION A:

☒ Patente de Invención
☐ Patente de Modelo de Utilidad
☐ Diseño Industrial
☐ Esquema de Trazado para Circuitos Integrados
☐ Marcas de Productos o Servicios

☐ Marca Colectiva
☐ Marca de Certificación
☐ Lema Comercial

2

SOLICITUD PUBLICADA

Número del expediente: **06-044002 08-11002**
Solicitante: **WORLD TRADE IMPORT-EXPORT WTIE AG**
Apoderado: **DILIA MARIA RODRIGUEZ DALEMAN**
Título de la nueva creación o denominación del signo:
"COMPOSICIÓN DE ISOFLAVONAS PARA TRATAMIENTO DE LOS SINTOMAS Y TRASTARNOS FISIOLÓGICOS DE LA MENUPAUSIA"
Gaceta: 605 de 30-06-2009, Número de Publicación 336

3

OPOSICION PRESENTADA POR:

OPOSITOR	Nombre: LAFRANCOL S.A. Dirección: Carrera 1 No. 46-84 Teléfono: (092) 449.30.51 Fax: Domicilio: Cali - Valle	IDENTIFICACION C.C. ☐ NIT ☒ C.E. ☐ Otro ☐ Número: 890 301 463 -8
REPRESENTANTE O APODERADO (74)	Nombre: TITO NOE PARRA MURILLO Dirección: CALLE 108 # 51-45 Teléfono: 7422525 E-mail: Fax: 7424092 Domicilio: Bogotá, D.C.	IDENTIFICACION C.C. ☒ NIT ☐ C.E. ☐ Otro ☐ Número: 79.579.680 de Bogotá TP 71168

4

FUNDAMENTOS DE LA OPOSICION:

Causal: Incumplimiento de requisitos de patentabilidad (Título II, Capítulo I, Decisión 486 de 2000).

Justificación: VER ANEXO

5

Comprobante de pago No. **09-71.400** (Oposición) Fecha: **23/SEP/2009**
(Prórroga) Fecha

TOTAL F
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5) Comprobante de pago:

Fecha:

10) Anexos:

☒ Comprobante de pago de la tasa de presentación de la solicitud

☒ Poderes, si fuese el caso

☐ Pruebas de los fundamentos de la oposición

☐ Documentos que acrediten el legítimo interés, si fuese el caso

☒ Certificado de Existencia y Representación legal de las partes, cuando sean personas jurídicas.

7)

NOMBRE

TITO NOE PARRA MURILLO

FIRMA:

C.C. N° 79.579.680 T.P. N° 71168 C.S.J.

Instrucciones para el diligenciamiento del presente formulario, ver reverso de esta página

35

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 09 - 71,400
FECHA : SEPTIEMBRE 23 DE 2009

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Act. 400 OPOSIOBSERVTER Folios: 20

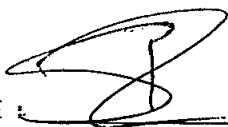
***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
LAFRANCOL S.A.	CONSIGNACION	BANCO DE BOGOTA	062754387	26744012	22/09/2009	1,148,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-04	PRESENTACION DE OBSERVACIONES	
		12 MARCAS Y LEMAS COMERCIALES	287,000.00
		TOTAL :	\$ 287,000.00

SON: DOSCIENTOS OCHENTA Y SIETE MIL PESOS

RESPONSABLE : 

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____