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NOTICE OF ALLOWANCE AND FEE(S) DUE

140619 7590 08/09/2019
Sullivan IP Solutions, LLC
PO Box 2252
New York, NY 10163

EXAMINER	
DAVIS, BRIAN J	
ART UNIT	PAPER NUMBER

1612

DATE MAILED: 08/09/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/938,837	03/28/2018	Alberto REINER	APR002US2	9958

TITLE OF INVENTION: MODIFIED RELEASE ORALLY ADMINISTERED AMINO ACID FORMULATIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	11/12/2019

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

140619 7590 08/09/2019
Sullivan IP Solutions, LLC
PO Box 2252
New York, NY 10163

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/938,837	03/28/2018	Alberto REINER	APR002US2	9958

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APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	11/12/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
DAVIS, BRIAN J	1612	514-399000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

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15/938,837	03/28/2018	Alberto REINER	APR002US2	9958
140619	7590	08/09/2019	EXAMINER	
Sullivan IP Solutions, LLC			DAVIS, BRIAN J	
PO Box 2252				
New York, NY 10163				
			ART UNIT	PAPER NUMBER
			1612	
DATE MAILED: 08/09/2019				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 15/938,837	Applicant(s) REINER et al.	
	Examiner BRIAN J DAVIS	Art Unit 1612	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to inventor's AF amendment (7/27/2019).
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are See Continuation Sheet. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov**.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file areply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.	

/BRIAN J DAVIS/ Primary Examiner, Art Unit 1612	8/4/2019
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Continuation of 3. The allowed claim(s) is/are: 1,10-12,15,17,24,73,74,80,83,88,91,93,96,100,104,106-109 [renumbered 1-21]

5 DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Objections Withdrawn

The objection to claim 1, outlined in the previous Office Action, has been overcome by inventor's amendment. The amendment corrects the claim text as appropriate.

Drawings

The objection to the drawings, maintained in the previous Office Action, has been overcome by inventor's amendment. The amendment supplies the proper labels.

Specification

The objection to the specification, maintained in the previous Office Action, has been overcome by inventor's amendment. The amendment corrects the text as appropriate.

112(b) Rejections Withdrawn

The rejections of claims 1, 10-12, 15, 17, 24, 73, 74, 80, 83, 88, 91, 93, 96, 100, 104 and 106-109 under 35 USC 112(b) or 35 USC 112 (pre-AIA), second paragraph,

outlined in the previous Office Action, have been overcome by inventor's amendment.

With respect to claims 1, 10-12, 15, 17, 24, 83, 88 and 106, the amendment clarifies the claim set as appropriate. With respect to the remaining claims (indefinite from indefinite), the rejection is moot.

Allowable Subject Matter

Claims 1, 10-12, 15, 17, 24, 73, 74, 80, 83, 88, 91, 93, 96, 100, 104 and 106-109 are allowed for reasons of record (6/25/2019).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN J DAVIS whose telephone number is (571)272-0638. The examiner can normally be reached on M-F 8:30-5:00 PM EDT.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass, can be reached at 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN J DAVIS/
Primary Examiner, Art Unit 1612
8/4/2019

OK TO ENTER: /B.J.D/

Docket No.: APR002US2
PATENT

08/04/2019

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Albert Reiner et al.

Customer No.: 140619

Application No.: 15/938,837

Confirmation No.: 9958

Filed: March 28, 2018

Art Unit: 1629

For: MODIFIED RELEASE ORALLY
ADMINISTERED AMINO ACID
FORMULATIONS

Examiner: Davis, Brian J.

AMENDMENT AFTER FINAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the FINAL REJECTION notified in this application on June 25, 2019, please enter the following amendments and consider the following remarks.

SPECIFICATION AMENDMENTS begin on page 2.

A REPLACEMENT CLAIM SET begins on page 3.

REMARKS begin on page 11.

SPECIFICATION AMENDMENTS

In the Examples, in the first paragraph of Example 1, please enter the following amendment:

MARKED REPLACEMENT PARAGRAPH

Table 1 lists ~~four~~ three separate representative amino acid mixtures for the dietary management of phenylketonuria, on a percentage basis.

CLEAN REPLACEMENT PARAGRAPH

Table 1 lists three separate representative amino acid mixtures for the dietary management of phenylketonuria, on a percentage basis.

REPLACEMENT CLAIM SET

- 1) (CURRENTLY AMENDED) An orally administered amino acid formulation comprising:
- a) one or more modified release amino acids;
 - b) hydroxymethylpropyl cellulose or ethylcellulose or a combination thereof integrally mixed with said amino acids; or
 - c) a coating on said modified release amino acids comprising ethylcellulose or a combination of ethylcellulose and glyceryl dibehenate;

wherein the formulation comprising 2 g of the modified release amino acids comprises a release profile releasing releases no more than 70% of the modified release amino acids in 30 minutes of dissolution testing performed in a <711> USP 39 NF 34, paddle apparatus, at 37 °C, in 450 or 500 mL, 0.1 N hydrochloric acid (pH 1.2), paddle speed 50 rpm, and said modified release is defined by said release profile.

2-9) CANCELLED

- 10) (PREVIOUSLY PRESENTED) The formulation of claim 1, comprising five or more of the following amino acids as modified release amino acids in the recited weight parts:

Amino Acid	Weight Parts
L-Alanine	2.0-12.0
L-Arginine	3.0-10.5
L-Aspartic Acid	5.0-10.5
L-Cystine	1.5-4.0
L-Glutamic Acid + Glutamine	7.0-25.0
Glycine	3.5-15.0
L-Histidine	2.0-6.5
L-Isoleucine	2.0-8.5
L-Leucine	8.0-15.0
L-Lysine	4.5-10.5
L-Methionine	1.0-3.0
L-Phenylalanine	4.0-7.5
L-Proline	3.5-15.0
L-Serine	2.0-8.5
L-Threonine	4.0-7.5
L-Tryptophan	1.0-4.0
L-Tyrosine	2.5-14.0
L-Valine	2.5-10.0
L-Carnitine	0.0-0.2
Taurine	0.05-1.0

- 11) (CURRENTLY AMENDED) The formulation of claim 10, comprising ten or more of the recited amino acids as modified release amino acids in the recited following weight parts:

Amino Acid	Weight Parts
L-Alanine	2.0-12.0
L-Arginine	3.0-10.5
L-Aspartic Acid	5.0-10.5
L-Cysteine	1.5-4.0
L-Glutamic Acid + Glutamine	7.0-25.0
Glycine	3.5-15.0
L-Histidine	2.0-6.5
L-Isoleucine	2.0-8.5
L-Leucine	8.0-15.0
L-Lysine	4.5-10.5
L-Methionine	1.0-3.0
L-Phenylalanine	4.0-7.5
L-Proline	3.5-15.0
L-Serine	2.0-8.5
L-Threonine	4.0-7.5
L-Tryptophan	1.0-4.0
L-Tyrosine	2.5-14.0
L-Valine	2.5-10.0
L-Carnitine	0.0-0.2
Taurine	0.05-1.0

- 12) (ORIGINAL) The formulation of claim 10, comprising fifteen or more of the recited amino acids as modified release amino acids in the recited weight parts.

13-14) CANCELLED

- 15) (PREVIOUSLY PRESENTED) The formulation of claim 10, comprising the recited essential amino acids, branched chain amino acids, and large neutral amino acids as modified release amino acids in the recited weight parts.

16) CANCELLED

- 17) (PREVIOUSLY PRESENTED) The formulation of claim 1, comprising five or more of the following amino acids as modified release amino acids in the recited weight parts:

Amino Acid	Weight Parts
L-Alanine	2.0-12.0
L-Arginine	3.0-10.5
L-Aspartic Acid	5.0-10.5
L-Cystine	1.5-4.0
L-Glutamic Acid + Glutamine	7.0-25.0
Glycine	3.5-15.0
L-Histidine	2.0-6.5
L-Isoleucine	2.0-8.5
L-Leucine	8.0-15.0
L-Lysine	4.5-10.5
L-Methionine	1.0-3.0
L-Phenylalanine	4.0-7.5
L-Proline	3.5-15.0
L-Serine	2.0-8.5
L-Threonine	4.0-7.5
L-Tryptophan	1.0-4.0
L-Tyrosine	2.5-14.0
L-Valine	2.5-10.0
L-Carnitine	0.0-0.2
Taurine	0.05-1.0

comprising 0.0 weight parts L-phenylalanine.

18-19) CANCELLED

20) CANCELLED

21-23) CANCELLED

24) (PREVIOUSLY PRESENTED) The formulation of claim 1, comprising five or more of the following amino acids as modified release amino acids in the recited weight parts

Amino Acid	Weight Parts
L-Alanine	2.0-12.0
L-Arginine	3.0-10.5
L-Aspartic Acid	5.0-10.5
L-Cystine	1.5-4.0
L-Glutamic Acid + Glutamine	7.0-25.0
Glycine	3.5-15.0
L-Histidine	2.0-6.5
L-Isoleucine	2.0-8.5
L-Leucine	8.0-15.0
L-Lysine	4.5-10.5
L-Methionine	1.0-3.0
L-Phenylalanine	4.0-7.5
L-Proline	3.5-15.0
L-Serine	2.0-8.5
L-Threonine	4.0-7.5
L-Tryptophan	1.0-4.0
L-Tyrosine	2.5-14.0
L-Valine	2.5-10.0
L-Carnitine	0.0-0.2
Taurine	0.05-1.0

comprising 0.0 weight parts L-phenylalanine and 0.0 weight parts L-tyrosine.

25-26) CANCELLED

27) CANCELLED

28-72) CANCELLED

73) (PREVIOUSLY PRESENTED) The formulation of claim 1 wherein the formulation is a powder or granulate.

74) (CURRENTLY AMENDED) The formulation of claim 1 in the form of a tablet, a pill, a soft or hard gelatin ~~capsule~~ capsules, a powder, a granulate, a microsphere, a lozenge, a sachet of packaged powders or granulates or microspheres, an elixir, a suspension, an emulsion, a chewable tablet, or a syrup.

75-79) CANCELLED

80) (PREVIOUSLY PRESENTED) The formulation of claim 1, wherein the formulation further comprises one or more additional ingredients selected from the group consisting of:

- a) vitamins, minerals and carbohydrates; or
- b) choline, inositol, vitamin A, vitamin D, vitamin E, vitamin K, vitamin C, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid,

potassium, calcium, magnesium, iron, zinc, copper, manganese, selenium, chromium, molybdenum, iodine, sodium, sulfur, phosphorus, docosahexaenoic acid, eicosapentaenoic acid, arachidonic acid, and lutein, and salts, chelates, and esters thereof.

81-82) CANCELLED

83) (CURRENTLY AMENDED) The formulation of claim 1 wherein the formulation comprising 2 g of the modified release amino acids comprises a release profile releasing ~~releases~~ no more than 60% of the modified release amino acids in 30 minutes of dissolution testing performed in a <711> USP 39 NF 34, paddle apparatus, at 37 °C, in 450 or 500 mL, 0.1 N hydrochloric acid (pH 1.2), paddle speed 50 rpm, and said modified release is defined by said release profile.

84-87) CANCELLED

88) (CURRENTLY AMENDED) An orally administered amino acid formulation comprising one or more modified release amino acids wherein the formulation comprising 2 g of the modified release amino acids comprises a release rate releasing ~~releases~~ no more than 70% of the modified release amino acids in 30 minutes of dissolution testing performed in a <711> USP 39 NF 34, paddle apparatus, at 37 °C, in 450 or 500 mL, 0.1 N hydrochloric acid (pH 1.2), paddle speed 50 rpm, wherein said modified release is defined by said release profile, wherein the modified release amino acids are granulates coated by from 5 wt% to 25 wt% of one or more release modifying excipients based on the weight of the amino acids, wherein each of the granulates comprise a plurality of modified release amino acids, and wherein said formulation comprises:

- a) hydroxymethylpropyl cellulose or ethylcellulose or a combination thereof integrally mixed with said amino acids; or
- b) a coating on said modified release amino acids comprising ethylcellulose or a combination of ethylcellulose and glyceryl dibehenate.

89-90) CANCELLED

91) (PREVIOUSLY PRESENTED) The formulation of claim 88 further comprising one or more release modifying excipients selected from ethylcellulose and a combination of ethylcellulose and glyceryl dibehenate.

92) CANCELLED

93) (PREVIOUSLY PRESENTED) The formulation of claim 88 further comprising:

- a) a bulking agent selected from lactose, sucrose, dextrose, sorbitol, fructose, and cellulose powder;
- b) a disintegrating agent selected from microcrystalline cellulose, starches, crospovidone, sodium starch glycolate, and crosscarmellose sodium;
- c) a glidant or lubricant selected from talc, corn starch, silicon dioxide, sodium lauryl sulfate, magnesium stearate, calcium stearate, sodium stearate, stearic acid, sodium stearyl fumarate, hydrogenated cotton seed oil, talc, waxes, cetyl alcohol, glyceryl stearate, glyceryl palmitate, glyceryl behenate, hydrogenated vegetable oils, and stearyl alcohol;
- d) a taste-masking agent selected from cellulose hydroxypropyl ethers (HPC); low-substituted hydroxypropyl ethers (L-HPC); cellulose hydroxypropyl methyl ethers (HPMC); methylcellulose polymers; Ethylcelluloses (EC) and mixtures thereof; Polyvinyl alcohol (PVA); hydroxyethylcelluloses; carboxymethylcelluloses and salts of carboxymethylcelluloses (CMC); polyvinyl alcohol and polyethylene glycol co-polymers; monoglycerides, triglycerides, polyethylene glycols, modified food starch, acrylic polymers and mixtures of acrylic polymers with cellulose ethers; cellulose acetate phthalate; sepi films such as mixtures of HPMC and stearic acid, cyclodextrins, and mixtures thereof;
- e) a flavoring agent selected from acacia syrup, acesulfame K, alitame, anise, apple, aspartame, banana, Bavarian cream, berry, black currant, butterscotch, calcium citrate, camphor, caramel, cherry, cherry cream, chocolate, cinnamon, bubble gum, citrus, citrus punch, citrus cream, cotton candy, cocoa, cola, cool cherry, cool citrus, cyclamate, cyclamate, dextrose, eucalyptus, eugenol, fructose, fruit punch, ginger, glycyrrhetinate, glycyrrhiza (licorice) syrup, grape, grapefruit, honey, isomalt, lemon, lime, lemon cream, monoammonium glycyrrhizinate, maltol, mannitol, maple, marshmallow, menthol, mint cream, mixed berry, neohesperidine DC, neotame, orange, pear, peach, peppermint, peppermint cream, raspberry, root beer, rum, saccharin, safrole, sorbitol, spearmint, spearmint cream, strawberry, strawberry

cream, stevia, sucralose, sucrose, sodium saccharin, saccharin, aspartame, neotame, acesulfame potassium, mannitol, talin, xylitol, sucralose, sorbitol, swiss cream, tagatose, tangerine, thaumatin, tutti frutti, vanilla, walnut, watermelon, wild cherry, wintergreen, xylitol, or a combination thereof;

- f) one or more release modifying excipients selected from the group consisting of ethylcellulose, glyceryl dibehenate, cellulose acetate, vinyl acetate/vinyl chloride copolymers, acrylate/methacrylate copolymers, polyethylene oxide, hydroxypropyl methylcellulose, carrageenan, alginic acid and salts thereof, hydroxyethyl cellulose, hydroxypropyl cellulose, karaya gum, acacia gum, tragacanth gum, locust bean gum, guar gum, sodium carboxymethyl cellulose, methyl cellulose, beeswax, carnauba wax, cetyl alcohol, hydrogenated vegetable oils, stearyl alcohol, acrylic acid copolymers, sodium alginate, carrageenan, alginic acid, pectin, sodium carboxymethyl cellulose, a starch derivative, or a combination thereof; or
- g) a binder selected from polyvinyl pyrrolidone, starch, methylcellulose, hydroxypropyl methylcellulose, carboxymethyl cellulose, sucrose solution, dextrose solution, guar gum, xanthan gum, acacia, tragacanth, locust bean gum and sodium alginate, or an alginic acid salt.

94-95) CANCELLED

- 96) (PREVIOUSLY PRESENTED) The formulation of claim 88 further comprising a binder selected from sodium alginate or an alginic acid salt.

97-99) CANCELLED

- 100) (PREVIOUSLY PRESENTED) The formulation of claim 1, wherein tyrosine in the formulation is not coated by a modified release coating.

101-103) CANCELLED

- 104) (PREVIOUSLY PRESENTED) A method of making a formulation of claim 88 comprising:

- a) providing a first mixture comprising a plurality of amino acids;
- b) contacting the mixture with a wetting agent and a binder to form a wet mixture;
- c) optionally passing the wet mixture through a sieve to form a uniform wet granulate;
- d) drying the uniform wet granulate to form a dry granulate;

- e) optionally passing the dry granulate through a sieve to form a uniform dry granulate; and
 - f) coating the uniform dry granulate with a modified release composition.
- 105) CANCELLED
- 106) (CURRENTLY AMENDED) An orally administered amino acid formulation comprising one or more modified release amino acids wherein the formulation comprising 2 g of the modified release amino acids comprises a release profile releasing ~~releases~~ no more than 70% of the modified release amino acids in 30 minutes of dissolution testing performed in a <711> USP 39 NF 34, paddle apparatus, at 37 °C, in 450 or 500 mL, 0.1 N hydrochloric acid (pH 1.2), paddle speed 50 rpm, wherein said modified release is defined by said release profile, wherein the modified release amino acids are granulates coated by from 5 wt% to 25 wt% of one or more release modifying excipients based on the weight of the amino acids, and wherein each of the granulates comprise a plurality of modified release amino acids, further comprising one or more release modifying excipients selected from ethylcellulose and a combination of ethylcellulose and glyceryl dibehenate.
- 107) (PREVIOUSLY PRESENTED) The formulation of claim 106 further comprising a binder selected from sodium alginate or an alginic acid salt.
- 108) (PREVIOUSLY PRESENTED) The formulation of claim 106, wherein tyrosine in the formulation is not coated by a modified release coating.
- 109) (PREVIOUSLY PRESENTED) The formulation of claim 106 comprising granulates having a size ranging from 0.1 to 1.5 mm.

REMARKS

Status of Claims

After the amendment, claims 1, 10-12, 15, 17, 24, 73, 74, 80, 83, 88, 91, 93, 96, 100, 104, and 106-109 are pending.

Claim 1 Objection

The Office objects to the presence of a period after limitation (c) in claim 1. Applicant has replaced the period with a semicolon and trusts it has satisfactorily addressed the objection.

Objection to Drawings

In response to the Examiner's objection to the drawings, Applicant is submitting herewith Replacement Sheets for Figures 1 and 2 with a "Prior Art" caption.

Objection to Specification

In response to the Examiner's objection to Example 1 in the specification, and its reference to four separate amino acid mixtures in Table 1 instead of three, Applicant has amended the text to refer to three separate amino acid mixtures."

35 U.S.C. 112(b) rejection

The Office Action also rejects the pending claims because the term "modified release" is allegedly unclear. As suggested by the examiner, Applicant has amended the independent claims to specifically state that the modified release is determined by the recited release rate.

CONCLUSION

Applicant believes the application is in condition for allowance and earnestly solicits a prompt notification of same. If there is any fee due in connection with the filing of this Amendment, please charge the fee to Deposit Account No. 600254.

Respectfully submitted,

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