ANDA 209499

**ANDA TENTATIVE APPROVAL**

Dr. Reddy's Laboratories, Inc.
107 College Road East
Princeton, NJ 08540
Attention: Robert Tambe
Vice President and Head, RA & QA, North America

Dear Robert Tambe:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 26, 2016, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Icosapent Ethyl Capsules, 0.5 gram and 1 gram.

Reference is also made to our letter dated August 7, 2020, granting final approval to your Icosapent Ethyl Capsules, 1 gram, and granting tentative approval to your Icosapent Ethyl Capsules, 0.5 gram, the complete response letter issued by this office on December 17, 2021, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. We have determined your Icosapent Ethyl Capsules, 0.5 gram, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Vascepa Capsules, 0.5 gram, of Amarin Pharmaceuticals Ireland, Limited (Amarin).

However, we are unable to grant final approval to your ANDA at this time because of the exclusivity issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the Agency at this time (e.g., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The RLD upon which you have based your ANDA, Amarin's Vascepa Capsules, 0.5 gram, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

| U.S. Patent Number | Expiration Date |
|---|---|
| 8,293,727 (the '727 patent) | February 9, 2030 |
| 8,293,728 (the '728 patent) | February 9, 2030 |
| 8,298,554 (the '554 patent) | April 29, 2030 |
| 8,314,086 (the '4,086 patent) | February 9, 2030 |
| 8,318,715 (the '715 patent) | February 9, 2030 |
| 8,357,677 (the '677 patent) | February 9, 2030 |
| 8,367,652 (the '652 patent) | February 9, 2030 |
| 8,377,920 (the '920 patent) | February 9, 2030 |
| 8,399,446 (the '446 patent) | February 9, 2030 |
| 8,410,086 (the '0,086 patent) | June 15, 2030 |
| 8,415,335 (the '335 patent) | February 9, 2030 |
| 8,426,399 (the '399 patent) | February 9, 2030 |
| 8,440,650 (the '650 patent) | February 9, 2030 |
| 8,445,003 (the '003 patent) | April 29, 2030 |
| 8,445,013 (the '013 patent) | April 29, 2030 |
| 8,454,994 (the '994 patent) | April 29, 2030 |
| 8,501,225 (the '225 patent) | April 29, 2030 |
| 8,518,929 (the '929 patent) | February 9, 2030 |
| 8,524,698 (the '698 patent) | February 9, 2030 |
| 8,546,372 (the '372 patent) | February 9, 2030 |
| 8,551,521 (the '521 patent) | April 29, 2030 |
| 8,563,608 (the '608 patent) | April 29, 2030 |

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|---|---|
| 8,617,593 (the '593 patent) | April 29, 2030 |
| 8,617,594 (the '594 patent) | April 29, 2030 |
| 8,623,406 (the '406 patent) | April 29, 2030 |
| 8,642,077 (the '077 patent) | April 29, 2030 |
| 8,669,245 (the '245 patent) | June 15, 2030 |
| 8,680,144 (the '144 patent) | February 9, 2030 |
| 8,691,871 (the '871 patent) | April 29, 2030 |
| 8,703,185 (the '185 patent) | April 29, 2030 |
| 8,709,475 (the '475 patent) | April 29, 2030 |
| 8,710,041 (the '041 patent) | June 15, 2030 |
| 9,198,892 (the '892 patent) | September 25, 2027 |
| 9,603,826 (the '826 patent) | June 28, 2033 |
| 9,610,272 (the '272 patent) | June 28, 2033 |
| 9,623,001 (the '001 patent) | June 28, 2033 |
| 9,693,984 (the '984 patent) | June 28, 2033 |
| 9,693,985 (the '985 patent) | June 28, 2033 |
| 9,693,986 (the '986 patent) | June 28, 2033 |
| 9,700,537 (the '537 patent) | May 31, 2027 |
| 9,918,954 (the '954 patent) | June 28, 2033 |
| 10,010,517 (the '517 patent) | April 29, 2030 |
| 10,265,287 (the '287 patent) | April 29, 2030 |
| 10,278,935 (the '935 patent) | June 28, 2033 |
| 10,278,936 (the '936 patent) | June 28, 2033 |

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|---|---|
| 10,278,937 (the '937 patent) | June 28, 2033 |
| 10,383,840 (the '840 patent) | June 28, 2033 |
| 10,555,924 (the '924 patent) | June 28, 2033 |
| 10,555,925 (the '925 patent) | June 28, 2033 |
| 10,568,861 (the '861 patent) | June 28, 2033 |
| 10,576,054 (the '054 patent) | June 28, 2033 |
| 10,668,042 (the '042 patent) | June 28, 2033 |
| 10,786,478 (the '478 patent) | June 28, 2033 |
| 10,792,267 (the '267 patent) | April 29, 2030 |
| 10,792,270 (the '270 patent) | June 28, 2033 |
| 10,842,766 (the '766 patent) | April 29, 2030 |
| 10,842,768 (the '768 patent) | June 15, 2030 |
| 10,881,632 (the '632 patent) | April 29, 2030 |
| 10,894,028 (the '028 patent) | June 28, 2033 |
| 11,000,499 (the '499 patent) | June 28, 2033 |
| 11,103,477 (the '477 patent) | April 29, 2030 |
| 11,116,742 (the '742 patent) | June 28, 2033 |
| 11,154,526 (the '526 patent) | April 29, 2030 |
| 11,213,504 (the '504 patent) | April 29, 2030 |
| 11,298,333 (the '333 patent) | June 28, 2033 |

With respect to: 1) the '593 and ‘406 patents (insofar as they pertain to the use code U-1287: method of reducing TG levels in patient suffering from severe hypertriglyceridemia); and 2) the '727, '728, '554, '4,086, '715, '677, '652, '920, '446, '335, '399, '650, '003, '013, '225, '929, '698, '372, '521, '608, and '594 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the

FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Icosapent Ethyl Capsules, 0.5 gram, under this ANDA. You have notified the Agency that Dr. Reddy's Laboratories, Inc. (Dr. Reddy's) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Dr. Reddy's for infringement of the '728, '715, '677, '652, '920, '335, '399, '650, '929, '698, '372 and '594 patents in the United States District Court for the District of Nevada [Amarin Pharma, Inc., et al. v. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Limited, Civil Action No. 18-01596]. On May 4, 2020, the court entered judgment in Civil Action No. 18-01596 that the asserted claims of the '728, '715, '677, '652, and '929 patents are invalid as obvious and dismissed all other claims with respect to the '920, '335, '399, '650, '698, '372, and '594 patents.[1]

With respect to: 1) the '593 patent (insofar as pertains to the use code U-2691: use of Vascepa to treat hypertriglyceridemia in an adult patient with elevated triglyceride (TG) levels (>= 150 mg/dL) and on statin therapy); 2) the '406 patent (insofar as it pertains to use code U-2692: use of Vascepa to reduce triglycerides in an adult patient with elevated triglyceride (TG) levels (>= 150 mg/dL) and on statin therapy); and the '0,086, '994, '077, '245, '144, '871, '185, '475, '041, '892, '826, '272, '001, '984, '985, '986, '537, '954, '517, '287, '935, '936, '937, '840, '924, '925, '861, '054, '042, '478, '267, '270, '766, '768, '632, '028, '499, '477, '742, '526, '504, and '333 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the FD&C Act that these are method-of-use patents that do not claim any indication for which you are seeking approval under your ANDA.

However, we are unable to grant final approval to your ANDA at this time. Prior to the submission of your ANDA, another applicant or applicants submitted a substantially complete ANDA providing for Icosapent Ethyl Capsules, 0.5 gram, and containing a paragraph IV certification. Your ANDA will be eligible for final approval on the date that is 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the FD&C Act.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

**RESUBMISSION**

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 3 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 3 months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities' compliance with cGMPs will be

classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available Agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review the changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after tentative approval, including changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED".

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information as specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book.

## ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions[2] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the *Federal Register* notice announcing facility fee amounts.

All finished dosage forms or active pharmaceutical ingredients manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of

misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

In addition, we note that GDUFA requires that certain non-manufacturing sites and organizations listed in generic drug submissions comply with the self-identification requirement. The failure of any facility, site, or organization to comply with its obligation to self-identify and/or to pay fees when due may raise significant concerns about that site or organization and is a factor that may increase the likelihood of a site inspection prior to approval. FDA does not expect to give priority to completion of inspections that are required simply because facilities, sites, or organizations fail to comply with the law requiring self-identification or fee payment.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact LCDR Daniil Marchuk, Regulatory Project Manager, at (240) 402 - 4322.

Sincerely yours,

*{See appended electronic signature page}*

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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[1] Judgment, *Amarin Pharma, Inc., et.al., v. Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories, LTD.*, Civil Action No. 18-01596 (D.NV., May 4, 2020), at 2 and 3.

[2] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Sarah Kurtz

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