Application No.	Drug	Applicant
NDA 020937	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Liebel-Flarsheim Co., LLC., 1034 South Brentwood Blvd., Suite 800, Richmond Heights, MO 63117.
NDA 020947	Pennsaid (diclofenac sodium) Topical Solution, 1.5% weight by weight (w/w).	Nuvo Pharmaceuticals, Inc., c/o Dwayne R.J. Moore, 41 Campus Dr., Suite 202, New Gloucester, ME 04260.
NDA 020975	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Liebel-Flarsheim Co., LLC.
NDA 020976	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Do.
NDA 021037	Magnevist (gadopentetate dimeglumine) Injection, 469.01 mg/mL.	Bayer HealthCare Pharmaceuticals, Inc.
NDA 021105	Sulfamethoxazole and Trimethoprim Tablets, 800 mg/160 mg; and Phenazopyridine HCL Tablets, 200 mg.	Able Laboratories, Inc., 1 Able Dr., Cranbury, NJ 08512.
NDA 021144	Ketek (telithromycin) Tablets, 300 mg and 400 mg	Sanofi-Aventis U.S., LLC., 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 021178	Glucovance (glyburide and metformin hydrocholoride (HCl)) Tablets, 1.25 mg/250 mg, 2.5 mg/500 mg, 5 mg/500 mg.	Bristol-Myers Squibb Co., P.O. Box 4000, Mail Stop: D.2341, Princeton, NJ 08543–4000.
NDA 021235	Prozac Weekly (fluoxetine delayed-release capsules) 90 mg.	Eli Lilly and Co.
NDA 021490	Femcon Fe (ethinyl estradiol and norethindrone tablets, 0.035 mg/0.4 mg; and ferrous fumarate tablets, 75 mg).	Allergan Pharmaceuticals International Limited, c/o Allergan Sales, LLC., 5 Giralda Farms, Madison, NJ 07940.
NDA 022011	Tyzeka (telbivudine) Tablets, 600 mg	Novartis Pharmaceuticals Corp.
NDA 022154	Tyzeka (telbivudine) Solution, 100 mg/5 mL	Do.
NDA 022328	Intermezzo (zolpidem tartrate) Sublingual Tablets, 1.75 mg and 3.5 mg.	Purdue Pharmaceutical Products L.P., 1 Stamford Forum, Stamford, CT 06901–3431.
NDA 050456	Statrol (neomycin sulfate and polymyxin B sulfate ophthalmic solution, USP) EQ 3.5 mg base/mL; equal to 16,250 units polymyxin B/mL.	Alcon Laboratories, Inc., 6201 South Freeway, Mail Stop: TC–45, Fort Worth, TX 76134–2099.
NDA 204553	ColPrep Kit (magnesium sulfate, potassium sulfate, and sodium sulfate) for Oral Solution, 1.6 grams (g)/3.13 g/17.5 g.	Gator Pharmaceuticals, Inc., 194 Inlet Dr., Saint Augustine, FL 32080.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of October 9, 2019. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on October 9, 2019 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19348 Filed 9–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6069]

Acceptance Review for De Novo Classification Requests; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Acceptance Review for De Novo Classification Requests.'' The purpose of this guidance is to explain the procedures and criteria FDA intends to use in assessing whether a request for an evaluation of automatic class III designation (De Novo classification request or De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review. This guidance discusses De Novo acceptance review policies and procedures, ''Refuse to Accept'' principles, and the elements of the De Novo Acceptance Checklist and the Recommended Content Checklist and is being issued to be responsive to an explicit deliverable identified in the Medical Device User Fee Amendments of 2017 (MDUFA IV).

DATES: The announcement of the guidance is published in the **Federal Register** on September 9, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the

public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6069 for ''Acceptance Review for De Novo Classification Requests.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Acceptance Review for De Novo Classification Requests'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Sergio de del Castillo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993–0002, 301–796–6419; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The automatic class III designation for devices of a new type occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the device. Any device that is of a new type that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976.

FDA may classify a device through the De Novo classification process, which is the pathway authorized under section 513(f)(2) of the FD&C Act. Upon receipt of a De Novo request, FDA is required to classify the device by written order (section 513(f)(2)(A)(iii) of the FD&C Act). The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Per section 513(f)(2)(B)(i) of the FD&C Act, the classification is the initial classification of the device for the purposes of section 513(f)(1) of the FD&C Act.

We believe De Novo classification enhances patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo classification process, the device can serve as a predicate for future devices of that type, including for 510(k)s (section 513(f)(2)(B)(i)). As a result, after a De Novo request is granted, other device sponsors do not have to submit a De Novo request or premarket application under section 515 of the FD&C Act (21 U.S.C. 360e)) in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), ''defining substantial equivalence''). Instead, other device sponsors can use the 510(k) process, when applicable, as a pathway to market their device.

FDA is issuing this guidance to provide clarity regarding the Agency's expectations for information to be submitted in a De Novo request and ensure predictability and consistency for sponsors. Focusing the Agency's review resources on complete De Novo requests will provide a more efficient approach to ensuring that safe and effective medical devices reach patients as quickly as possible. Moreover, with the enactment of MDUFA IV, FDA agreed to issuance of draft and final guidance, which includes a submission checklist to facilitate a more efficient and timely review process to assist with new performance goals. Acceptance review therefore takes on additional importance in both encouraging quality applications from De Novo requesters and allowing the Agency to appropriately concentrate resources on complete applications.

FDA anticipates that the Agency and industry may need a period of time to operationalize the policies within this guidance. Therefore, if all criteria necessary to meet a minimum threshold of acceptability for De Novo requests as

outlined in this guidance are not included in a De Novo request received by FDA before or up to 60 days after the publication of this guidance, FDA staff does not generally intend to refuse to accept.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of October 30, 2017 (82 FR 50144). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Acceptance Review for De Novo Classification Requests.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or from the Center for Biologics Evaluation and Research at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Acceptance Review for De Novo Classification Requests'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16055 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR Part; guidance; or FDA form	Topic	OMB control No.
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
3	Combination products; Request for Designation	0910–0523
807, 812, and 814	Human Subject Protection; Acceptance of Data from Clinical Studies for Medical Devices.	0910–0741
54 (Forms FDA 3454 and 3455)	Financial disclosure by clinical investigators	0910–0396

Dated: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19350 Filed 9–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–4186]

Determination That CALCIMAR (calcitonin salmon) Injection, 200 International Units Per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CALCIMAR (calcitonin salmon) Injection, 200 International Units per milliliter (IU/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for CALCIMAR (calcitonin salmon) Injection, 200 IU/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 301–796–3472.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CALCIMAR (calcitonin salmon) injection, 200 IU/mL, is the subject of NDA 017769, held by Sanofi Aventis, and initially approved on April 17, 1978. CALCIMAR is indicated for Paget's disease of bone, hypercalcemia, and postmenopausal osteoporosis.

CALCIMAR (calcitonin salmon) injection, 200 IU/mL, is currently listed