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FDA considered comments received on the draft guidance that appeared in the **Federal Register** of October 30, 2017 (82 FR 50144).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

in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated December 1, 2016 (Docket No. FDA–2016–P–4186), under 21 CFR 10.30, requesting that the Agency determine whether CALCIMAR (calcitonin salmon) injection, 200 IU/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CALCIMAR (calcitonin salmon) injection, 200 IU/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CALCIMAR (calcitonin salmon) injection, 200 IU/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CALCIMAR (calcitonin salmon) injection, 200 IU/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CALCIMAR (calcitonin salmon) injection, 200 IU/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19347 Filed 9–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcing Call for Nominations for Members of the President's Council on Sports, Fitness & Nutrition Science Board

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) seeks nominations of qualified candidates to serve as members of the President's Council on Sports, Fitness & Nutrition Science Board.

DATES: Nominations for membership on the Science Board will be accepted through 11:59 p.m. E.T. on October 11, 2019.

ADDRESSES: Nominations should be submitted by email to *sports@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Katrina L. Piercy, Ph.D., R.D., Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite 420; Rockville, MD 20852; Telephone: (240) 453–8280. Email: *odphpinfo@hhs.gov*.

SUPPLEMENTARY INFORMATION: The Science Board is a subcommittee of the President's Council on Sports, Fitness & Nutrition (the Council) and is made up of Council members and scholars with expertise in the fields of physical activity, health, sports, and nutrition. The role of the Science Board is to assist the Council by providing scientific guidance. For the 2020–2021 term, the Science Board will focus its efforts around the Council's and HHS's implementation and dissemination of the *National Youth Sports Strategy* and youth sports-related topics. The main duties of the Science Board will be to: (a) Provide subject matter expertise on youth sports and related disciplines; (b) draft content for publication (*e.g.,* blogs, peer-reviewed articles) to various audiences highlighting specific youth sports topics; and (c) participate virtually in Science Board meetings and presentations to the Council.

Nominations: HHS will consider nominations, including self-nominations, for Science Board members of individuals qualified to carry out the above-mentioned tasks. Science Board members must hold a Ph.D., MD, or related terminal degree in the fields of physical activity, health, sports, and/or nutrition. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) The name, address, daytime telephone number, and email address of the nominator and the individual being nominated; (2) a letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee that the nominee is willing to serve as a member of the Science Board; and (3) a current copy of the nominee's curriculum vitae (CV) no more than 10 pages in length. Inclusion of the following is requested in the CV: (1) Academic appointment; (2) current and/or past grant awards; (3) publications showing breadth and experience in areas of specialization; (4) paid and non-paid board and advisory appointments; and (5) education and occupational history.

All nominations must include the required information. Incomplete nominations will not be processed for consideration. All nomination information should be sent in a single email, with attachments, to *sports@hhs.gov.* All nominations must be submitted by 11:59 p.m. E.T on Friday, October 11, 2019.

Equal opportunity practices regarding membership appointments to the Science Board will be aligned with HHS policies. When possible, every effort will be made to ensure that the Science Board is a diverse group of individuals with representation from various geographic locations, racial and ethnic minorities, all genders, and persons with disabilities. Individuals will be appointed to serve as members of the Science Board to represent balanced viewpoints of the scientific evidence, not to represent the viewpoints of any specific group.

Dated: August 22, 2019.

Donald Wright,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

[FR Doc. 2019–19384 Filed 9–6–19; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as