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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3767]

Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Immunology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on scientific issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 13 and 14, 2019, from 8 a.m. to 6 p.m.

ADDRESSES: Doubletree by Hilton DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900. The hotel's website is at: <https://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-washington-dc-north-gaithersburg-GAIGWDT/index.html>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comments on this meeting. The docket number is FDA–2019–N–3767. The docket will close on December 16, 2019. Submit either electronic or written comments on this public meeting to the docket by December 16,

2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 16, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submission) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before October 28, 2019, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://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 Submission” 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–2019–N–3767 for “Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.” FDA 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.

FOR FURTHER INFORMATION CONTACT:

Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993-0002, 301-796-0400, FDA.MetalImplants@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On November 13 and 14, 2019, the committee will discuss the topic of immunological responses to metal-containing products regulated as medical devices. The discussion will focus on metal-containing implants as well as dental amalgam. Implants are medical devices that are placed into a surgically or naturally formed opening of the human body and are intended to remain there after the procedure for an extended period of time (typically, greater than 30 days). For decades, metal-containing implants have been used in a large number of medical specialties including cardiology, orthopedics, dentistry, gastroenterology, and neurology or neurosurgery. Recent postmarket issues with some metal-on-metal orthopedic implants and gynecological metal-containing implants have raised questions about the potential for some patients to develop unexpected or heightened biological responses to the implant. These may include local (peri-implant) adverse events and potentially systemic manifestations, which may impact a patient's quality of life and necessitate medical or surgical intervention. While not considered an implant, dental amalgam is included in this discussion

because of its potential for patient and user exposure to mercury compounds and some purported similarities in the adverse biological responses and clinical manifestations elicited by some dental amalgams to that of traditional metal implants.

FDA is convening this committee to promote an open public discussion of, and seek expert opinion on, currently available scientific and clinical data pertaining to the biological responses to metal implants and dental amalgam and the potential associated clinical sequelae. The committee will be asked to discuss and provide recommendations regarding:

- The extent immunological responses to certain metals may cause or contribute to device-related local and systemic adverse effects as well as the potential underlying mechanism(s) involved and corresponding clinical manifestations.
- Patient characteristics, metal types, and/or anatomical considerations that may put an individual at higher risk for a heightened immunological response to a metal-containing implant, and methods that may assist in their identification.
- Mitigations that may reduce the risk for unintended immunological responses, including changes to device composition and design.
- The evidentiary gaps in biomedical research and clinical/diagnostic management associated with immunological responses to metal implants.
- The adequacy, conclusions, and evidence gaps identified by a systemic literature review aimed to assess the recent epidemiologic and clinical evidence on adverse health effects reported in relation to occupational or non-occupational exposure to dental amalgam.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

FDA plans to provide a live webcast of the November 13 and 14, 2019, meeting of the Immunology Devices

Panel. While the Center for Devices and Radiological Health is working to make webcasts available to the public, there may be instances where the webcast transmission is not successful; staff will work to reestablish the transmission as soon as possible. The link for the webcast is available at: <https://collaboration.fda.gov>. Further information regarding the webcast, including the web address for the webcast, will be made available at least 2 days in advance of the meeting at the following website:

November 13, 2019: <http://fda.yorkcast.com/webcast/Play/390aea8fa1db4d42ba59e514b24e8f301d>.

November 14, 2019: <http://fda.yorkcast.com/webcast/Play/d4174e54b00e4f7ab8ffb3ec8c99d3f51d>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All written and electronic submissions made to the docket on or before October 28, 2019, will be provided to the panel. Oral presentations from the public will be scheduled on November 13, 2019, between approximately 2:15 p.m. and 3:15 p.m., and on November 14, 2019, between approximately 8:15 a.m. and 9:15 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 16, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 17, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a

disability, please contact AnnMarie Williams, at AnnMarie.Williams@fda.hhs.gov or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4329]

Determination That KENALOG (Triamcinolone Acetonide) Ointment, 0.025% and 0.1%, and Other Drug Products Were 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 the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

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 approved 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 generally known as the “Orange Book.” Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 011600	KENALOG	Triamcinolone Acetonide ..	0.025%; 0.1%	Ointment; Topical	Mylan Pharmaceuticals, Inc.
NDA 012827	ROBINUL	Glycopyrrolate	1 milligram (mg)	Tablet; Oral	Casper Pharma LLC.
NDA 018029	ROBINUL FORTE	Glycopyrrolate	2 mg	Tablet; Oral	
NDA 018029	RITALIN-SR	Methylphenidate Hydrochloride	20 mg	Extended-Release Tablet; Oral	Novartis Pharmaceuticals, Corp.
NDA 018164	ANAPROX	Naproxen Sodium	Equivalent to (EQ) 250 mg Base	Tablet; Oral	ATNAHS Pharma U.S., Ltd.
NDA 018405	AYGESTIN	Norethindrone Acetate	5 mg	Tablet; Oral	Teva Branded Pharmaceutical Products R&D, Inc.
NDA 018452	SEPTRA	Sulfamethoxazole; Trimethoprim	16 mg/milliliter (mL); 80 mg/mL	Injectable; Injection	Monarch Pharmaceuticals, Inc.
NDA 018703	ZANTAC 150	Ranitidine Hydrochloride	EQ 150 mg Base	Tablet; Oral	GlaxoSmithKline.
NDA 018703	ZANTAC 300	Ranitidine Hydrochloride	EQ 300 mg Base	Tablet; Oral	
NDA 019111	TUSSIONEX PENNKINETIC	Chlorpheniramine Polistirex; Hydrocodone Polistirex	EQ 8 mg Chlorpheniramine Maleate/5 mL; EQ 10 mg Hydrocodone Bitartrate/5 mL	Extended-Release Suspension; Oral	UCB, Inc.
NDA 019507	KERLONE	Betaxolol Hydrochloride	10 mg; 20 mg	Tablets; Oral	Sanofi-Aventis U.S. LLC.
NDA 019537	CIPRO	Ciprofloxacin Hydrochloride	EQ 100 mg Base; EQ 750 mg Base	Tablet; Oral	Bayer Healthcare Pharmaceuticals, Inc.
NDA 019937	ADENOCARD	Adenosine	3 mg/mL	Injectable; Injection	Astellas Pharma U.S., Inc.
NDA 020415	REMERON	Mirtazapine	45 mg	Tablet; Oral	Organon USA, Inc.
NDA 020528	MAVIK	Trandolapril	1 mg; 2 mg; 4 mg	Tablet; Oral	AbbVie, Inc.
NDA 020864	MAXALT	Rizatriptan Benzoate	EQ 5 mg Base	Tablet; Oral	Merck Sharp & Dohme Corp.
NDA 020865	MAXALT-MLT	Rizatriptan Benzoate	EQ 5 mg Base	Orally Disintegrating Tablet; Oral	Do.
NDA 020945	NORVIR	Ritonavir	100 mg	Capsule; Oral	AbbVie, Inc.
NDA 021131	ZYVOX	Linezolid	400 mg/200 mL (2 mg/mL)	Injectable; Injection	Pharmacia & Upjohn Co.