from whole animal tissue, or produced in vitro, synthetically or through recombinant expression, and often serve as signaling molecules for many physiologic functions that are regulated by endogenous proteins. Peptides can exhibit distinct combinations of characteristics regarding their chemistry, pharmacology, sites of action, pharmacokinetic disposition, and pharmacodynamics. Although FDA has been regulating peptides for decades, there is a growing appreciation for specific considerations for the design and conduct of clinical pharmacology studies to assess peptides, such as those designed to evaluate the effects of organ impairment or drug interactions. Currently, there are no FDA-published guidance documents on clinical pharmacology assessments that contain specific recommendations for peptides.[2]

II. Request for Information and Comments

Interested persons are invited to provide detailed information and comments on certain aspects of evaluating the clinical pharmacology of peptides. For all questions, organize any discussion by the type of peptide (*e.g.,* isolated from animal source, or produced in vitro, synthetically or through recombinant expression) and route of administration. Please provide the rationale for your suggestions and include supporting data if available. FDA is particularly interested in responses to the following overarching questions:

(1) Under what circumstances should the following assessments be warranted or not warranted for peptides?

(a) Evaluating pharmacokinetics-based drug-drug interactions (DDIs)

(b) Evaluating the pharmacokinetics in hepatic impairment

(c) Evaluating immunogenicity and its impact on pharmacokinetics, safety, and efficacy

(d) Evaluating QT prolongation

(2) In circumstances where the assessments above are warranted, what types of assessments are suitable and why? What are the study design considerations (*e.g.,* in vitro test systems, population, analytes, immunogenicity risk assessment, immunogenicity assay development and validation) for the types of assessments discussed in the following items? Please describe the rationale for any design considerations proposed.

(a) For evaluating pharmacokinetics-based DDIs (*e.g.,* in vitro studies, dedicated clinical studies, including cocktail studies, population pharmacokinetic analyses), please discuss the advantages, challenges, and limitations for these assessments.

(b) For evaluating pharmacokinetics in hepatic impairment (*e.g.,* dedicated clinical studies, population pharmacokinetic analyses), please discuss the advantages, challenges, and limitations for these assessments.

(c) For evaluating immunogenicity and its impact on pharmacokinetics, safety, and efficacy (*e.g.,* antibodies against the active ingredient peptide, peptide-related impurities, or endogenous counterpart, if present, neutralizing activity and antibody titers, cytokine measurements), please discuss the advantages, challenges, and limitations for these assessments.

(d) For evaluating cardiac electrophysiology (*e.g.,* hERG inhibition assay, thorough QT assessment) in nonclinical or clinical studies, please discuss the advantages, challenges, and limitations for these assessments.

(3) Are there other clinical pharmacology considerations for peptides not covered in the questions above, such as use of pharmacodynamic biomarkers and/or pharmacokinetic assessments for dose selection? If yes, provide a description and rationale for any proposed considerations, as well as approaches, advantages, challenges, and limitations for the assessment.

The public comments collected will help FDA develop recommendations for the design and conduct of clinical pharmacology studies important to the understanding of the safe and effective use of peptides and facilitate the regulatory assessment of such studies.

III. Electronic Access

Persons with access to the internet may obtain relevant clinical pharmacology guidances at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: May 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10179 Filed 5–13–21; 8:45 am]

BILLING CODE 4164–01–P

[2] There is an FDA draft guidance entitled ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin'' (October 2017) that is specific for ANDA applications for chemically synthetized peptides that refers to listed drugs of rDNA origin; available at *https://www.fda.gov/media/107622/download.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1440]

Oncologic Drugs 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 Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory 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 June 24, 2021, from 10:30 a.m. to 2:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1440. The docket will close on June 23, 2021. Submit either electronic or written comments on this public meeting by June 23, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 23, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 23, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) 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 June 10, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and

consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2020–N–1440 for ''Oncologic Drugs 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, 240–402–7500.

- 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 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 the 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: She-Chia Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–5343, Fax: 301–847–8533, *ODAC@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: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss biologics license application (BLA) 761209, for retifanlimab injection, submitted by Incyte Corporation. The proposed indication (use) for this product is for the treatment of adult patients with locally advanced or metastatic squamous carcinoma of the anal canal (SCAC) who have progressed on or who are intolerant of platinum-based chemotherapy.

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 on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before June 10, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Eastern Time. 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 June 2, 2021. 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 June 3, 2021.

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 She-Chia Chen (see **FOR FURTHER INFORMATION CONTACT**) 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: May 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10181 Filed 5–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0306]

Determination That OVIDE (Malathion) Lotion, 0.5%, 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 OVIDE (malathion) lotion, 0.5%, was 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 this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 240–825–9944, *Kaetochi.Okemgbo@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 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.

OVIDE (malathion) lotion, 0.5%, is the subject of NDA 018613, held by Taro Pharmaceutical Industries, Ltd., and initially approved on August 2, 1982. OVIDE is indicated for patients infected with *Pediculus humanus capitis* (head lice and their ova) of the scalp hair.

In a letter dated August 19, 2019, Taro Pharmaceutical Industries Ltd. notified FDA that OVIDE (malathion) lotion, 0.5%, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Encube Ethicals Private Ltd. submitted a citizen petition dated March 19, 2021 (Docket No. FDA–2021–P–0306), under 21 CFR 10.30, requesting that the Agency determine whether OVIDE (malathion) lotion, 0.5%, 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 OVIDE (malathion) lotion, 0.5% was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that OVIDE (malathion) lotion, 0.5%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of OVIDE (malathion) lotion, 0.5%, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list OVIDE (malathion) lotion, 0.5%, 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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: May 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10166 Filed 5–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0341]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Safety; Federal-State Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of