exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the FD&C Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988.

| Panels | Function |
|---|---|
| Dental Products Panel (one representative—to represent the dental drug industry). | Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational products for use in dentistry, endodontics or bone physiology relative to the oral and maxillofacial area and makes appropriate recommendations to the Commissioner of Food and Drugs. |
| Ear, Nose, and Throat Devices Panel ..... | Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational ear, nose, and throat devices and makes appropriate recommendations to the Commissioner of Food and Drugs. |
| General and Plastic Surgery Devices Panel ..... | Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general and plastic surgery devices and makes appropriate recommendations to the Commissioner of Food and Drugs. |
| Hematology and Pathology Devices Panel ..... | Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine including pathology, hematology, histopathology, cytotechnology and molecular biology and makes appropriate recommendations to the Commissioner of Food and Drugs. |
| Orthopaedic and Rehabilitation Devices Panel .. | Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational orthopedic and rehabilitation devices and makes appropriate recommendations to the Commissioner of Food and Drugs. |

## II. Qualifications

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

## III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

## IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nomination must include a current, complete résumé or curriculum vitae for each nominee including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory panel for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the particular device panels listed in the table. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: December 2, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–26276 Filed 12–4–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–5464]**

### Novel Excipient Review Program Proposal; Request for Information and Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for information and comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of a docket to obtain information and comments that will assist the Agency in determining whether it should establish a pilot program for the toxicological and

quality evaluation of novel excipients intended for use in human drugs. The Agency hopes to obtain information and comments on several aspects of such a program before deciding whether to develop it.

**DATES:** Submit written or electronic comments and information on the notice by February 3, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 3, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 3, 2020. 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.

*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–2019–N–5464 for ''Novel Excipient Review Program Proposal; Request for Information and 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.'' 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.

**FOR FURTHER INFORMATION CONTACT:** Karen Davis Bruno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6428, Silver Spring, MD 20993–0002, 301–796–1199, *karen.davisbruno@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

We use the term ''excipient'' in this notice to mean any ingredient intentionally added to a drug product (including biological drug products) that is not intended to exert therapeutic effects at the intended dosage, although it may improve product delivery (see FDA guidance for industry ''Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients'' (Excipients guidance), May 2005, p. 1 (available at *https://www.fda.gov/media/72260/download*)). The term ''inactive ingredient'' is often used to mean the same thing. Examples of excipients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents (see Excipients guidance, pp. 1–2). For purposes of this notice, FDA would expect a novel excipient to be an excipient that has not been previously used in FDA-approved drug products and that does not have established use in food.

FDA reviews excipients used in a drug product as part of an investigational new drug application (IND) or a marketing application to determine whether they are safe for use in human pharmaceuticals. Historically, FDA has not reviewed the safety of novel excipients outside the context of an IND, a new drug application (NDA), or a biologics license application (BLA) describing a finished product to which the excipient has been added.[1]

Stakeholders have encouraged FDA to establish a program for the submission and review of toxicological and quality data supporting the use of novel excipients in drug products outside the context of an IND, an NDA, or a BLA. They state that certain novel excipients may provide public health benefits, such as improved drug delivery or utility in abuse-deterrent opioid formulations, for example. Proponents of an FDA novel excipient review program believe FDA's recognition of a novel excipient would reassure drug developers that the novel excipient can be used in a drug development program

[1] A proposed drug product that contains an excipient that would require clinical investigations to establish safety of the excipient for use in a particular drug product would not be permitted in an abbreviated new drug application (ANDA) but may be submitted in a 505(b)(2) application.

while minimizing the risk that safety concerns would be raised by FDA during application review. They have also cited a perceived risk aversion on the part of drug developers, such that novel excipients may be avoided in drug development programs, even when the excipients have potential public health benefits.

With this information in mind, FDA's Center for Drug Evaluation and Research is considering developing a pilot program for the toxicological and quality evaluation of novel excipients. The Agency seeks information and comment on several aspects of such a program before deciding whether to develop it.

## II. Possible Approach To Reviewing Novel Excipients

FDA is considering establishing a pilot program that would review a limited number of submissions per year. Any program developed by the Agency would be voluntary. FDA recognition of a novel excipient would not be necessary for the novel excipient to be included in a finished drug product described in an IND, an NDA, or a BLA.

Generally, FDA anticipates that a submission to a potential novel excipient review program would include toxicological studies supporting the safety of the novel excipient at anticipated levels and duration of exposure, by anticipated routes of administration. Additionally, FDA anticipates that submitters would provide identification and control information, including compositional and purity specifications for the novel excipient (see Excipients guidance).

FDA recognition of a novel excipient would mean that, based on a review of safety, manufacturing, and compositional information, FDA has determined that the proposed context of use (*e.g.,* acute or chronic exposure by specified route(s) of administration up to specified amounts) is expected to be safe. This determination would obviate the need for FDA review of the excipient in the context of an IND if its use in the investigational product is consistent with the recognized context of use. In the case of an NDA or a BLA seeking marketing approval or licensure of a finished drug or biological product containing a recognized excipient, FDA would review all information in the application relating to safety of the finished product. FDA expects that excipients reviewed under this program, after they are used in approved formulations, would be listed in the Inactive Ingredient Database.

## III. Requested Information and Comments

Interested persons are invited to provide detailed comment on all aspects of this issue. Please read the information above regarding the submission of comments and confidential information. FDA is particularly interested in responses to the following questions:

1. What drug development challenges do drug sponsors encounter that could be addressed by using novel excipients?

2. Can stakeholders identify examples (specific or general) of novel excipients that have potential public health benefits?

3. FDA anticipates that a novel excipient recognition program would be limited to excipients that do not have a well-established history of safe use in food and that have potential public health benefits. We would be interested in stakeholder comment on these criteria.

4. Would FDA recognition of a novel excipient be sufficient to overcome any reluctance on the part of drug developers to use the novel excipient in a drug development program? Do drug development sponsors also look for a history of safe use in marketed drug products?

5. FDA envisions that an individual excipient manufacturer participating in a novel excipient recognition program would submit a complete package of safety data and certain chemistry, manufacturing, and controls information to support FDA's recognition of a novel excipient. This data and information would be based upon nonclinical studies of sufficient quality and quantity to allow for a safety evaluation, consistent with the Excipients guidance. We would be interested in stakeholder comment on this approach.

6. Are there adequate incentives for excipient manufacturers to engage in this process, particularly in situations in which multiple manufacturers may be undertaking to develop closely related novel excipients? If not, what incentives would encourage excipient manufacturers to engage in this process?

7. What information, if any, should FDA affirmatively disclose about a novel excipient evaluated under an eventual program in order to ensure the success of the program? For example, should FDA's evaluation be posted and explained publicly? Please note that FDA would handle disclosure of information submitted under the program in accordance with applicable law.

Dated: December 2, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–26266 Filed 12–4–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2019–E–1059; FDA–2019–E–1060; and FDA–2019–E–1061]**

## Determination of Regulatory Review Period for Purposes of Patent Extension; ANDEXXA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ANDEXXA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claims that human biological product.

**DATES:** Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 3, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 2, 2020. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 3, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 3, 2020. 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.

*Electronic Submissions*

Submit electronic comments in the following way: