monograph, approval of the application and patient access to the drug were delayed because the USP–NF standards development processes did not accept proposals from applicants requesting changes to compendial standards for products that were not currently approved by FDA. If a monograph needed to be revised to include the applicant's proposed specifications, there were no mechanisms to do this until after the application was approved. For approval, the product would have to be shown to meet the current monograph, at least for identity, and the product label would have to indicate differences from the monograph regarding strength, quality, or purity. Typically, the revised monograph would not become official for 6 months or more. The USP–PMP was created to address these issues.

Under the USP–PMP, applicants that have successfully filed an NDA, ANDA, NADA, or ANADA with FDA and are awaiting review and approval can propose revisions to an existing monograph or can propose the publication of a new monograph for an article that is not currently part of the official compendia. MF holders referenced in a successfully filed NDA, ANDA, NADA, or ANADA may also propose revisions to an existing monograph or propose publication of a new monograph for their drug substance. Immediately following FDA approval of a specific NDA, ANDA, NADA, or ANADA, USP will make available a revised monograph (or new monograph, as applicable) harmonized with the application's approved quality specifications. This process results in the creation of compendial standards that are harmonized with the quality specifications in an approved application. (Note: Initiation of the USP–PMP does not confer Agency acceptability of the compendial standards proposed for the product, nor preclude full application evaluation by the Agency; all applications will be subject to complete evaluation using current established review practices.)

This guidance details the Agency's expectations for applicants (and MF holders referenced by applications awaiting approval) who choose to use the USP–PMP. The document explains how applicants (and MF holders) should initiate the process, provides Agency recommendations, and addresses some common situations that may arise during use of the USP–PMP.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process.'' 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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 relating to NDAs and ANDAs in 21 CFR part 314, including 21 CFR 314.50, 314.94, and 314.420, have been approved under OMB control number 0910–0001. The collections of information relating to NADAs in 21 CFR part 514, including 21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, 514.11, and 558.5 have been approved under OMB control number 0910–0032. The collections of information relating to ANADAs in sections 512(b)(2) and (n)(1) of the FD&C Act (21 U.S.C. 360b(b)(2) and (n)(1)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, or https://www.regulations.gov.*

Dated: July 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14781 Filed 7–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0331]

Live Case Presentations During Investigational Device Exemption Clinical Trials; Guidance for Institutional Review Boards, Industry, Clinical Investigators, 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 ''Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials.'' The purpose of this guidance is to provide institutional review boards (IRBs), industry, clinical investigators, and FDA staff with factors to consider when evaluating the appropriateness of a live case presentation within a clinical investigation conducted under an investigational device exemption (IDE) application. This document provides guidance on important information about a live case presentation that should be provided as part of an original IDE application or a supplement to an IDE application when requesting inclusion of a live case presentation during a clinical investigation.

DATES: The announcement of the guidance is published in the **Federal Register** on July 11, 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–2014–D–0331 for ''Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials.'' 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 ''Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: John Doucet, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993–0002, 301–796–6474.

SUPPLEMENTARY INFORMATION:

I. Background

A live case presentation is a live or pre-recorded broadcast of a surgical or percutaneous procedure, typically narrated by the operator (or a discussant other than the operator), with or without expert panel and/or audience interaction. Our expectation is that very few investigations under an IDE will include live case presentations. However, by increasing awareness of the study for healthcare professionals and eligible subjects, live case presentations may lead to new therapies being made available sooner.

This guidance is intended, in part, to improve the quality of information about live case presentations submitted by sponsors as part of an investigational plan in an original IDE application or supplement to an IDE application, or to the IRB for non-significant risk studies, and to ensure consistency in the review of those submissions. It describes measures we recommend sponsors take to ensure adequate human subject protection, followup, reporting, and data analysis for live case presentations.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of April 17, 2014 (79 FR 21776). 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 live case presentations during IDE clinical trials. 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1736 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 have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
812	Investigational Device Exemption	0910–0078
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910–0755
56	Institutional Review Boards	0910–0130

Dated: July 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14765 Filed 7–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2397]

Using the Inactive Ingredient Database; Draft Guidance for Industry; 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 draft guidance for industry entitled ''Using the Inactive Ingredient Database.'' This draft guidance describes FDA's Inactive Ingredient Database (IID) and provides recommendations for how to use the IID in the development of drug products. It is intended to give applicants a clearer understanding of the information provided in the IID and its terminology.

DATES: Submit either electronic or written comments on the draft guidance by October 9, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2019–D–2397 for ''Using the Inactive Ingredient Database.'' 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Zuk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6162, Silver Spring, MD 20993–0002, 240–402–9133, *Susan.Zuk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Using the Inactive Ingredient Database.'' Industry may use the information in FDA's IID to support the safety of an excipient, which can affect application filing and scientific review. Inclusion in the IID is evidence that the excipient has previously been used in FDA-approved drug products. If an excipient has been used in approved drug products for a particular route of administration, the excipient generally is not considered new and may warrant less extensive assessment the next time it is included in a new drug product for the same route of administration. This information is useful to industry when developing new drug products. The draft guidance explains how to use the IID in the development of drug products.

The draft guidance explains the meaning of terms used in the IID. It describes the information users will find in the IID for each excipient. It explains the link between FDA's Global Substance Registration System and nomenclature in the IID to facilitate ingredient searches. The draft guidance also clarifies terminology used in the IID, such as ''maximum potency,'' how that information is described for certain dosage forms, and when potency information is not provided.