of the FD&C Act: August 11, 2016. The applicant claims August 10, 2016, as the date the new drug application (NDA) for INGREZZA (NDA 209241) was initially submitted. However, FDA records indicate that NDA 209241 was submitted on August 11, 2016.

3. *The date the application was approved:* April 11, 2017. FDA has verified the applicant's claim that NDA 209241 was approved on April 11, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 552 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04545 Filed 3–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4750]

The ''Deemed To Be a License'' Provision of the Biologics Price Competition and Innovation Act: Questions and Answers; 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 final guidance for industry entitled ''The 'Deemed To Be a License' Provision of the BPCI Act: Questions and Answers.'' This guidance is intended to provide answers to common questions about FDA's implementation of the statutory provision under which an application for a biological product approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as of March 23, 2020, will be deemed to be a license for the biological product under the Public Health Service Act (PHS Act) on March 23, 2020. This guidance also describes FDA's compliance policy for the labeling of biological products that will be the subject of deemed biologics license applications (BLAs). This guidance is intended to facilitate planning for the March 23, 2020, transition date and provide further clarity regarding the Agency's implementation of this statutory provision. This guidance finalizes the draft guidance of the same title issued on December 12, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on March 5, 2020.

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–2015–D–4750 for ''The 'Deemed To Be a License' Provision of the BPCI Act: Questions and Answers.'' 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.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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Janice Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6270, Silver Spring, MD 20993–0002, 301–796–3475, *Janice.Weiner@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911, *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''The 'Deemed to be a License' Provision of the BPCI Act: Questions and Answers.'' This guidance is intended to provide answers to common questions about FDA's implementation of the ''transition'' provision of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) under which an application for a biological product approved under section 505 of the FD&C Act (21 U.S.C. 355) as of March 23, 2020, will be deemed to be a license for the biological product under section 351 of the PHS Act (42 U.S.C. 262) on March 23, 2020 (''the transition date''). This guidance also describes FDA's compliance policy for the labeling of biological products that will be the subject of deemed BLAs. This guidance is intended to facilitate planning for the transition date and provide further clarity regarding the Agency's implementation of this statutory provision.

Although the majority of therapeutic biological products have been licensed under section 351 of the PHS Act, some protein products historically have been approved under section 505 of the FD&C Act. On March 23, 2010, the BPCI Act was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148). The BPCI Act clarified the statutory authority under which certain protein products will be regulated by amending the definition of a ''biological product'' in section 351(i) of the PHS Act to include a ''protein (except any chemically synthesized polypeptide),'' and describing procedures for submission of a marketing application for certain ''biological products.'' Section 605 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), further amended the definition of a ''biological product'' in section 351(i) of the PHS Act to remove the parenthetical ''(except any chemically synthesized polypeptide)'' from the statutory category of ''protein.'' In the **Federal Register** of February 21, 2020, FDA issued a final rule that amends its regulation that defines ''biological product'' to incorporate changes made by the BPCI Act and the Further Consolidated Appropriations Act, 2020, and to provide its interpretation of the statutory term ''protein'' (85 FR 10057). This rule is effective on March 23, 2020. FDA also has previously stated its interpretation of the statutory term ''protein'' in the amended definition of ''biological product'' (see FDA's draft guidance for industry entitled ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)'' (December 2018), available on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* (''Biosimilar Q&A Draft Guidance'')).[1]

The BPCI Act requires that a marketing application for a ''biological product'' (that previously could have been submitted under section 505 of the FD&C Act) must be submitted under section 351 of the PHS Act; this requirement is subject to certain exceptions during a 10-year transition period ending on March 23, 2020 (see section 7002(e)(1) to (3) and (e)(5) of the BPCI Act). On March 23, 2020, an approved application for a biological product under section 505 of the FD&C Act shall be deemed to be a license for the biological product under section 351 of the PHS Act (see section 7002(e)(4) of the BPCI Act).[2]

In the **Federal Register** of December 12, 2018 (83 FR 63894), FDA invited comment on the preliminary list of approved applications for biological products under the FD&C Act that will be affected by the transition provision (''Preliminary List'') (available on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*). FDA explained that if an application holder or other person believes that an approved new drug application (NDA) should be added to the list or should not be included on the list, the application holder or other person should submit a comment to the public docket established for this Q&A guidance and the list. FDA posted updates to the Preliminary List on September 23, 2019, and January 15, 2020.

In the **Federal Register** of December 12, 2018, FDA also invited comment on the factors that FDA should consider in determining whether a combination product composed of a biological product constituent part and a drug constituent part will be subject to the transition provision. However, FDA did not receive any substantive comments on this topic. The current Preliminary List includes a small number of drug-biologic combination products and complex mixtures assigned to the Center for Drug Evaluation and Research, which reflects the Agency's current thinking that the approved NDAs for these products are appropriately subject

[1] FDA also described its interpretation of the statutory term ''chemically synthesized polypeptide'' in the Biosimilar Q&A Draft Guidance and the proposed rule entitled ''Definition of the Term 'Biological Product' '' (83 FR 63817, December 12, 2018); however, this interpretation is no longer necessary to our interpretation of the statutory term ''biological product'' in light of the amendment made by section 605 of the Further Consolidated Appropriations Act, 2020.

[2] Section 607 of the Further Consolidated Appropriations Act, 2020, amended section 7002(e)(4) of the BPCI Act to provide that FDA will continue to review an application for a biological product under section 505 of the FD&C Act after March 23, 2020, so long as that application was submitted under section 505 of the FD&C Act, is filed not later than March 23, 2019, and is not approved as of March 23, 2020. If such an application is approved under section 505 of the FD&C Act before October 1, 2022, it will be deemed to be a license for the biological product under section 351 of the PHS Act upon approval (see section 7002(e)(4)(B)(iii) and (vi) of the BPCI Act).

to the transition provision. FDA's evaluation of each of these approved NDAs for drug-biologic combination products or complex mixtures was informed by a general consideration of the factors used to determine the appropriate marketing application type for antibody-drug conjugates (see FDA's guidance for industry entitled ''Questions and Answers on Biosimilar Development and the BPCI Act'' (December 2018), available on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*).

To ensure that the Agency considers any additional comments on the list before the statutory transition date, the January 2020 update to the Preliminary List recommended that application holders or other interested persons submit either electronic or written comments no later than February 19, 2020.

This guidance finalizes the draft guidance entitled ''The 'Deemed to be a License' Provision of the BPCI Act: Questions and Answers'' issued on December 12, 2018 (83 FR 63894). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) Providing information on updating the listing information for the biological product in FDA's electronic Drug Registration and Listing System between March 23, 2020, and June 30, 2020; (2) clarifying that, in the absence of other changes made by the application holder that would require a new National Drug Code (NDC) number, biological products approved under the FD&C Act will retain their current NDC number after the NDA is deemed to be a BLA; (3) providing information on establishment standards for ''non-specified biological products'' that are the subject of deemed BLAs; (4) clarifying the process for submitting followup reports on or after March 23, 2020, for any initial field alert report submitted before March 23, 2020; and (5) clarifying certain aspects of FDA's compliance policy for the labeling of biological products that are the subject of deemed BLAs. In addition, technical changes were made for consistency with the revisions to the PHS Act and the BPCI Act enacted in sections 605 and 607 of the Further Consolidated Appropriations Act, 2020, and editorial changes were made to improve clarity.

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 ''The 'Deemed To Be a License' Provision of the BPCI Act: Questions and Answers.'' 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3521). The collections of information in 21 CFR part 314 have been approved under 0910–0001; the collections of information in 21 CFR parts 601 and 610 have been approved under 0910–0338; the collections of information in 21 CFR 600.80 through 600.90 have been approved under 0910–0308; and the collections of information in 21 CFR 201.56, 201.57, and 201.80 have been approved under 0910–0572. In addition, the collections of information for applications submitted under section 351(k) of the PHS Act have been approved under 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov*.

Dated: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04537 Filed 3–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0370]

Guidance for Industry: Exocrine Pancreatic Insufficiency Drug Products—Submitting New Drug Applications; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of a guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs,'' which was issued in 2006. The guidance set forth the Agency's thinking on data and information that may support a new drug application (NDA) for a proposed pancreatic enzyme product (PEP) that contains pancreatin or pancrelipase and is intended for the treatment of exocrine pancreatic insufficiency (EPI). FDA is withdrawing the guidance because an NDA for such a product may not be submitted after March 23, 2020. Sponsors interested in submitting a biologics license application (BLA) for a proposed PEP should contact the Agency with any questions.

DATES: The withdrawal is effective March 23, 2020.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: FDA is withdrawing the guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs,'' which was issued in 2006 (see 71 FR 19524 (April 14, 2006)). The guidance described FDA's thinking regarding the data and information that may support submission of NDAs, including submission of NDAs pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(2)), for products that contain the ingredients pancreatin or pancrelipase and are used to treat EPI.

Pancreatic enzyme preparations of porcine or bovine origin that contain the ingredients pancreatin or pancrelipase have a long history of use for the treatment of EPI in children and adults with cystic fibrosis and chronic pancreatitis. These products have been available in the United States for decades, largely marketed as unapproved drugs. On April 28, 2004 (69 FR 23410), however, FDA announced that all orally administered PEPs are new drugs that must be approved via a marketing application for prescription use only, and explained the conditions for continued marketing of these drug products. The guidance explained FDA's thinking regarding ways in which sponsors of products containing pancreatin and pancrelipase could design drug development programs to demonstrate the safety and effectiveness of their products and satisfy the requirements for approval of an NDA, including an NDA submitted pursuant to section 505(b)(2) of the FD&C Act.

Although most therapeutic biological products have been licensed under section 351 of the Public Health Service Act (PHS) (42 U.S.C. 262), some protein products historically have been