transitioning the current table format ''Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations'' to a searchable, public-facing online database (available on the FDA website at *https://purplebooksearch.fda.gov/*).

As part of FDA's commitment to encouraging innovation and competition among biological products and the development of biosimilars, and to fulfill goals described in the letter entitled ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,'' (available on the FDA website at *https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf*) and commitments described in the Biosimilar Action Plan (available on the FDA website at *https://www.fda.gov/media/114574/download*), FDA has created the Purple Book database. The new database provides the public with timely information about FDA-licensed biological products, including biosimilar and interchangeable products, through a dynamic, accessible, easy-to-use online search engine. This expanded Purple Book will offer more information about approved biological products, including information about whether a biological product is a reference product for a licensed biosimilar or interchangeable product, in a user-friendly format to help users quickly identify FDA-approved biosimilar and interchangeable products.

The initial Purple Book Version 1.0 announced on February 24, 2020 contains a limited data set that includes all approved biosimilars products and their related reference products, with simple search and advanced search functionality. The goal of the initial release is to gather stakeholder feedback and conduct user testing on the new database to inform the next phases of development. FDA intends to release additional phased enhancements to the database. Taking user testing and stakeholder input into consideration, the enhanced Purple Book is expected ultimately to include all Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) regulated biological products, including transition products, in addition to enhanced functionality. A later release of the enhanced Purple Book will include determinations that have been made pertaining to exclusivity.

The new Purple Book database is intended to improve transparency and functionality for stakeholders by providing a complete view of biological product options, including biosimilar and interchangeable products, and to advance public awareness about licensed biological products.

FDA is committed to making the Purple Book database interactive, user-friendly, and functional for multiple stakeholders with varying information needs. FDA is publishing this **Federal Register** notice and opening a docket to gather public comment on this version of the database. At the close of the comment period, the Agency will collect this feedback for consideration as additional functionality and improvements are developed and implemented.

FDA welcomes any relevant information that stakeholders and other members of the public wish to share. FDA is particularly interested in input on how the Agency can improve the Purple Book database in future releases, including on the questions set forth below.

1. How user-friendly is the information in the new Purple Book database?

a. Are navigation resources and instructions user-friendly?

b. Do the definitions and hover overs (information available when a person positions a computer cursor over an image or icon without selecting it) assist in your understanding?

2. Does the new Purple Book database help improve understanding of available biological product options among patients, payors, clinicians, and other parties?

a. What additional information or modifications could improve understanding about available biological product options?

3. Which functionalities of the new database are most useful to patients, payors, clinicians, and other parties (*e.g.,* simple search results, advanced search results, hover over definitions, monthly historical data change reports, data download capabilities)?

a. Which aspects of the simple search functionality are most useful for navigating the database and which need improvement?

b. Which aspects of the advanced search functionality are most useful for navigating the database and which need improvement?

c. What other modifications or enhancements could improve the new database's functionality or usability?

4. Are there other types of information or functionalities that would be useful to include in the Purple Book database?

II. Electronic Access

Persons with access to the internet may access the Purple Book at *https://purplebooksearch.fda.gov/.*

Dated: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04539 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–2017–E–6571]

Determination of Regulatory Review Period for Purposes of Patent Extension; INGREZZA

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 INGREZZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug 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 May 4, 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 September 1, 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 May 4, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 4, 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–2017–E–6571 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; INGREZZA.'' 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, INGREZZA (valbenazine tosylate) indicated for the treatment of adults with tardive dyskinesia. Subsequent to this approval, the USPTO received a patent term restoration application for INGREZZA (U.S. Patent No. 8,039,627) from Neurocrine Biosciences, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated February 6, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of INGREZZA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for INGREZZA is 2,071 days. Of this time, 1,827 days occurred during the testing phase of the regulatory review period, while 244 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* August 12, 2011. The applicant claims August 16, 2011, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 12, 2011, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505*

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