505(j)(5)(F), 505A (21 U.S.C. 355a), 505E (21 U.S.C. 355f), 506H (21 U.S.C. 356h), and 527 (21 U.S.C. 360cc) of the FD&C Act; see also 21 CFR 314.108, 316.31, 316.34). The exclusivities identified above are set forth on a product-specific basis in the Orange Book. This information is used by a wide range of stakeholders, including applicants of ANDAs and 505(b)(2) applications, in planning product development.

The Orange Book also plays an essential administrative role in FDA's implementation of recent statutory provisions related to drug product regulation. For example, section 505(j)(12) of the FD&C Act, added by the FDA Reauthorization Act of 2017 (Pub. L. 115–52) (FDARA), requires FDA to publish on its website and update at least every 6 months a list of approved NDA products that are off-patent and off-exclusivity, and for which FDA has not approved an ANDA referencing that NDA drug product, and FDA uses the Orange Book to populate this list. Section 506I of the FD&C Act requires NDA and ANDA holders to provide a written notification to FDA 180 days prior to withdrawing an approved drug from sale, to provide written notification to FDA within 180 days of the date of approval of a drug if that drug will not be available for sale within 180 days of the date of approval, and to have reviewed information in the Orange Book and submitted a one-time marketing status report. This information is used by FDA to move drugs that are not available for sale from the ''Prescription Drug Product List'' to the ''Discontinued Drug Product List'' in the Orange Book (see section 506I(e) of the FD&C Act).

FDA has historically sought to update and enhance the Orange Book to make it more accessible and useful to regulated industry and the public. Below are examples of updates FDA has made to the publication:

- In 1985, FDA added to the Orange Book a list of OTC drug products that have been approved in NDAs or ANDAs.
- In 1997, FDA published the Orange Book on the internet.
- In 2003, FDA started publishing an indicator as to whether a listed patent contains drug substance and/or drug product claims.
- In 2005, FDA made the Orange Book available for download off the Agency's website.
- In 2005, FDA switched from publishing patent listings in a public docket to publishing them daily in the Orange Book.
- In 2005, FDA switched from publishing generic drug approvals monthly to publishing them daily.
- In 2015, FDA launched a mobile application, ''Orange Book Express,'' to put timely information in the hands of those using smartphones and tablets.
- In 2016, FDA redesigned the Orange Book website to include commonly used features on the home page and to allow users to better navigate the Orange Book and customize their search.
- In 2017, FDA revised the Orange Book so that drug listings now clarify which listed drugs are RLDs and which are reference standards (see § 314.3(b)), as well as to clarify which products in the ''Discontinued Drug Product List'' may be referred to as an RLD.
- In 2017, FDA revised the Orange Book to include listed patent submission dates, when available.
- In 2017, FDA added the patent disputes list to the Orange Book website, which informs stakeholders which patents have been disputed by an outside party to FDA.
- In 2018, FDA updated the Orange Book to include descriptions indicating which indication(s) are protected by orphan drug exclusivity.

As part of FDA's Drug Competition Action Plan [1] and our continued effort to provide more accessible and useful information in the Orange Book, FDA is considering whether there are other opportunities to enhance the publication. The Drug Competition Action Plan aims to facilitate more generic competition, promote patient access, and improve the economics of developing generic medicines. Soliciting public comment on this topic will help guide the Agency's priorities as we consider enhancing the Orange Book.

II. Establishment of a Public Docket and Request for Comments

FDA is establishing a public docket to solicit input from a broad group of stakeholders, including patients, health care providers, drug manufacturers, public policy makers (*e.g.,* Federal and State health agencies), individuals involved in patent litigation (*e.g.,* patent counsel), and any other interested parties, on whether and how the Orange Book can be improved. (To note, FDA intends to publish a separate **Federal Register** notice seeking public input specifically on patent listings in the Orange Book in the near future, and thus is not soliciting comment on that topic now.) In addition to general comments, FDA is interested in responses to the following questions:

- What types of people or entities use the Orange Book?
- What sections of the Orange Book do these different types of people or entities use?
- For what reasons do these people or entities use the Orange Book? What additional information or features (*e.g.,* additional search functions) could be incorporated into the Orange Book to make it more useful?
- Is the information in the Orange Book regarding therapeutic equivalence generally useful?
  - How useful is the second letter of a therapeutic equivalence evaluation code?
  - How could the therapeutic equivalence information be made more user-friendly or otherwise be tailored to meet the needs of people or entities that use the Orange Book (*e.g.,* the therapeutic equivalence evaluation code)?
  - If you use the information regarding therapeutic equivalence, how do you use it?
  - Does the information regarding therapeutic equivalence promote drug competition? And if so, how?
- Is there any other information regarding the Orange Book that would be useful for FDA to consider?

Dated: May 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11683 Filed 5–29–20; 8:45 am]

BILLING CODE 4164–01–P

[1] Available at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1068]

Orange Book—Questions and Answers; 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 ''Orange Book—Questions and Answers.'' This guidance is intended to assist interested parties (including prospective drug product applicants, drug product applicants, and approved application holders) in utilizing the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the

Orange Book). This guidance provides answers to commonly asked questions FDA has received from interested parties regarding the Orange Book.

DATES: Submit either electronic or written comments on the draft guidance by August 31, 2020 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–2020–D–1068 for ''Orange Book—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 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: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Orange Book—Questions and Answers.'' This guidance is intended to assist interested parties (including prospective drug product applicants, drug product applicants, and approved application holders) in utilizing the Orange Book. This guidance provides answers to commonly asked questions FDA has received from interested parties regarding the Orange Book.

The Orange Book identifies drug products approved by FDA under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information. The main criteria for the inclusion of a drug product in the Orange Book are that the drug product is the subject of an approved application and that FDA has not determined the drug product to have been withdrawn from sale for safety or effectiveness reasons. In addition, the Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education on drug product selection and to foster containment of health care costs.

This guidance provides answers to questions that have been received by FDA staff that manage the Orange Book. The questions and answers cover the following topics: General inquiries about the content and format of the Orange Book, petitioned abbreviated new drug applications, the movement of drug products between different sections in the Orange Book, and patent listings.

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 ''Orange Book—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 draft guidance refers to previously approved FDA 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. 3501–3521). The collections of information in 21 CFR 314.50(a) through (f), (i), (h), and (k) and 314.94 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 314.50(h), 314.53, Form FDA 3542, and Form FDA 3542a, have been approved under OMB control number 0910–0513.

III. Electronic Access

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

Dated: May 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11682 Filed 5–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1127]

Listing of Patent Information in the Orange Book; 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 or Agency) is announcing the establishment of a docket to solicit comments on the listing of patent information in the FDA publication, ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the ''Orange Book''). We are soliciting comments on the types of patents currently listed in the Orange Book and the impact that any change to current patent listing practices may have on drug product development. This notice is not intended to communicate our regulatory expectations on these issues but is instead intended to seek early input from the public to inform further regulatory action if determined to be appropriate.

DATES: Submit either electronic or written comments by August 31, 2020.

ADDRESSES: FDA is establishing a docket for public comments on this document. The docket number is Docket No. FDA–2020–N–1127. The docket will close on August 31, 2020. Submit either electronic or written comments by that date. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 31, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 31, 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.

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–1127 for ''Listing of Patent Information in the Orange Book.'' 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.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993, 240–402–7930, *Elizabeth.Giaquinto@fda.hhs.gov.*