http://www.regulations.gov by searching for and locating Docket No. FAA–2019–0119.

(2) For more information about this AD, contact Aziz Ahmed, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: 516–287–7329; fax: 516–794–5531; email: *Aziz.Ahmed@faa.gov*.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Bombardier Service Bulletin 670BA–53–056, dated February 11, 2016.

(ii) [Reserved]

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com;* internet *http://www.bombardier.com*.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Des Moines, Washington, on June 18, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–14416 Filed 7–5–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA–2019–D–2733]

Compliance Policy for Certain Compounding of Oral Oxitriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency; Immediately in Effect Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of an immediately in effect guidance for industry entitled ''Compliance Policy for Certain Compounding of Oral Oxitriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency.'' This guidance describes FDA's policy concerning the conditions under which the Agency does not generally intend to take regulatory action against a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician using the bulk drug substance oxitriptan (also known as 5-hydroxytryptophan or 5-HTP) to compound oral drug products for patients with tetrahydrobiopterin (BH4) deficiency. FDA developed this guidance in response to communications from pharmacists and caregivers regarding the use of oxitriptan to treat patients with BH4 deficiency following issuance of a final rule that placed oxitriptan on the list of substances that cannot be used to compound drug products in accordance with certain compounding provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on July 8, 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–2019–D–2733 for ''Compliance Policy With Respect to Certain Compounding of Oral Oxitriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency.'' 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 guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993–0002, 855–543–3784 or 301–796–3400; Fax: 301–431–6353, email: *druginfo@fda.hhs.gov*. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tracy Rupp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5171, Silver Spring, MD 20993, 240–402–0260.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an immediately in effect guidance for industry entitled ''Compliance Policy for Certain Compounding of Oral Oxitriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency.'' This guidance describes FDA's policy concerning the conditions under which the Agency does not generally intend to take regulatory action against a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician using the bulk drug substance oxitriptan to compound oral drug products for patients with BH4 deficiency.

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician to qualify for exemptions from certain requirements of the FD&C Act related to FDA approval prior to marketing, current good manufacturing practice requirements, and labeling with adequate directions for use (see sections 505, 501(a)(2)(B), and 502(f)(1) of the FD&C Act (21 U.S.C. 355, 351(a)(2)(B), and 352(f)(1))). One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that: (1) Comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by FDA; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by FDA, appear on a list of bulk drug substances developed by FDA through regulation. (See section 503A(b)(1)(A)(i) of the FD&C Act.)

On February 19, 2019, FDA issued a final rule (84 FR 4696) (''February 19, 2019, final rule''), which established the list of bulk drug substances that can be used to compound drug products under section 503A of the FD&C Act even though they are not the subject of an applicable USP or NF monograph or a component of an FDA approved drug product (the 503A Bulks List). (See section 503A(b)(1)(A) of the FD&C Act.) The final rule, codified at § 216.23 (21 CFR 216.23), placed six bulk drug substances on the 503A Bulks List (§ 216.23(a)), and identified four others, including oxitriptan, that cannot be used to compound drug products under section 503A of the FD&C Act (§ 216.23(b)). Additional bulk drug substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of future rulemaking.

FDA developed this guidance in response to communications from pharmacists and caregivers regarding the use of oxitriptan to treat patients with BH4 deficiency following issuance of the February 19, 2019, final rule, which placed oxitriptan on the list of bulk drug substances that cannot be used to compound drug products under section 503A of the FD&C Act. According to those communications and other information available to the Agency, oxitriptan is the standard of care for the treatment of BH4 deficiency, which is caused by several different rare enzyme defects that result from gene mutations. BH4 deficiency is also known as: Primary tetrahydrobiopterin deficiency, atypical phenylketonuria (PKU), GTP cyclohydrolase (GTPCH) deficiency, 6-pyruvoyl-tetrahydropterin synthase (6-PTPS) deficiency, and dihydropteridine reductase (DHPR) deficiency. FDA did not consider BH4 deficiency during its initial review of this substance for the 503A Bulks List. Thus, this guidance addresses the conditions under which FDA does not intend to take regulatory action against a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician for the use of bulk oxitriptan to compound oral drug products for the treatment of identified individual patients with BH4 deficiency provided certain conditions are met. In light of the new information regarding use of oral oxitriptan to treat BH4 deficiency, FDA is considering whether to reevaluate the exclusion of oxitriptan from the 503A Bulks List.

FDA is issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate due to the public health need for patients with BH4 deficiency to access compounded oxitriptan oral drug products (21 CFR 10.115(g)(2)). This guidance does not establish any rights for any person and is not binding on FDA or the public. Although this guidance is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the document at either *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: July 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14355 Filed 7–5–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket Number USCG–2016–0989]

RIN 1625–AA01

Anchorage Regulations; Passagassawakeag River, Belfast, ME

AGENCY: Coast Guard, DHS.

ACTION: Final rule.