P&A	Program officer	Email address
Wyoming	Katherine Cargill-Willis	*Katherine.Cargill-Willis@acl.hhs.gov.*

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on April 23, 2021. Letters of Assurance should be submitted electronically via email and have an electronic time stamp indicating the date/time submitted.

VII. Agency Contacts

1. Programmatic Issues

Direct programmatic inquiries to your program officer listed above or Ophelia McLain at *Ophelia.mclain@acl.hhs.gov.*

2. Submission Issues

Direct inquiries regarding submission of the Letters of Assurance to the appropriate ACL Program Officer found in the table in ''Section IV. Submission Information.''

Dated: April 5, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021–07292 Filed 4–8–21; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0039]

Electronic Submissions; Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing the availability of version 2.2 of the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports (ICSRS) for Vaccines (Specifications). The version update is not applicable to CBER-regulated drug products marketed for human use with approved New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs); CBER-regulated therapeutic biological products marketed for human use with approved Biologic License Applications (BLAs); Whole Blood or blood components; and human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under the Public Health Service Act.

ADDRESSES: You may submit either electronic or written comments 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–2021–N–0039 for ''Electronic Submissions; Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification''. 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, 240–402–7500.

- 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 laws. 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

CBER is announcing the availability of version 2.2 of the Specifications for Preparing and Submitting Postmarket ICSRs for Vaccines (available at *https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation*). The version update has been prepared to accommodate the submission of certain reports for combination products required by an FDA rule, ''Postmarketing Safety Reporting for Combination Products'', published in the **Federal Register** of December 20, 2016 (81 FR 92603) (available at *https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products*). In addition, version 2.2 includes updated business rules (Appendix I of the Specifications) which provide details on data field specifications as well as updated sample Extensible Markup Language (XML) ICSR test files (available at *https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation*). The version update is not applicable to CBER-regulated drug products marketed for human use with approved NDAs and ANDAs; CBER-regulated therapeutic biological products marketed for human use with approved BLAs); Whole Blood or blood components; and HCT/Ps regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264).

Vaccine manufacturers and others responsible for reporting ICSRs for vaccines can now transition to reporting in the updated version 2.2. Instructions to transition are available at *https://www.fda.gov/vaccines-blood-biologics/getting-started-icsr-submission-fdas-electronic-vaccine-adverse-event-reporting-system-evaers.* Manufacturers can contact the CBER ICSR Submissions Coordinator (*CBERICSRSubmissions@fda.hhs.gov*) to inform of their intent to transition to version 2.2 of the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines. Although manufacturers are encouraged to transition to the updated version 2.2, CBER continues to accept reports in version 1.0 until further notice.

Dated: April 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07332 Filed 4–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1816]

Lavipharm Laboratories, Inc., et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple holders of those ANDAs. The basis for the withdrawal is that these ANDA holders have repeatedly failed to file required annual reports for those ANDAs and have failed to satisfy the requirement to have an approved risk evaluation and mitigation strategy (REMS).

DATES: Approval is withdrawn as of April 9, 2021.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). Additionally, in accordance with section 505–1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1), the Agency determined that a REMS is necessary for all the applicable listed drugs that the ANDAs in table 1 reference to ensure the benefits of the listed drugs outweigh the risks. In accordance with section 505–1(i) of the FD&C Act, an ANDA is required to have a REMS if the applicable listed drug has an approved REMS.

In the **Federal Register** of September 25, 2020 (85 FR 60474), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of these five ANDAs because the holders of these ANDAs had repeatedly failed to submit the required annual reports and have failed to receive approval of a REMS for their products. The holders of these ANDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes a waiver of the opportunity for hearing by the holders of the ANDAs concerning the proposal to withdraw approval of their ANDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the five applications listed in table 1 of this document.

TABLE 1—ANDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED AND A REMS HAS NOT BEEN APPROVED

Application No.	Drug	Applicant
ANDA 077051 ..	Fentanyl transdermal system film, extended-release, 25 micrograms (mcg)/hour (hr), 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr.	Lavipharm Laboratories, Inc., 69 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 085217 ..	Acetaminophen and Codeine Phosphate Tablet, 325 milligrams (mg)/30 mg.	Everylife, 2021 15th Avenue West, Seattle, WA 98119.
ANDA 085638 ..	Acetaminophen, Aspirin, and Codeine Phosphate Capsule, 150 mg/180 mg/60 mg.	Scherer Laboratories, Inc., 2301 Ohio Dr., Suite 234, Plano, TX 75093.
ANDA 085639 ..	Acetaminophen, Aspirin, and Codeine Phosphate Capsule, 150 mg/180 mg/30 mg.	Do.
ANDA 085640 ..	Acetaminophen, Aspirin, and Codeine Phosphate Capsule, 150 mg/180 mg/15 mg.	Do.