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]

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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.

FDA finds that the holders of the ANDAs listed in table 1 have repeatedly failed to submit reports required by §§ 314.81 and 314.98 and section 505(k) of the FD&C Act (21 U.S.C. 355). Furthermore, the holders of the ANDAs listed in table 1 have failed to receive approval of a REMS for their products in accordance with section 505–1 of the FD&C Act. In addition, under § 314.200, FDA finds that the holders of the ANDAs have waived their opportunity for a hearing and any contentions concerning the legal status of the drug products. Therefore, based on these findings and pursuant to the authority under section 505(e) of the FD&C Act, approval of the ANDAs listed in table 1 and all amendments and supplements thereto is hereby withdrawn as of April 9, 2021.

Dated: April 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07335 Filed 4–8–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1031]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 10, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0249. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Recall Regulations—21 CFR Part 7

OMB Control Number 0910–0249—Extension

This information collection helps support implementation of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) pertaining to product recalls, and regulations in part 7 (21 CFR part 7), subpart C promulgated to clarify and explain associated practices and procedures. Sections 7.49, 7.50, and 7.59 (21 CFR 7.49, 7.50, and 7.59) apply specifically to product recalls, which may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Agency. Recalls are terminated when all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy. The regulations also provide for corrective actions to be taken regarding violative products and establish specific requirements that enable us to monitor and assess the adequacy of a firm's efforts in this regard. The provisions include reporting to FDA on the initiation and termination of a recall, as well as submitting recall status reports and making required communication disclosures. Specific guidance regarding recalls is set forth in § 7.59, although product-specific guidance documents may also be developed to assist respondents to the information collection. Agency guidance documents are issued in accordance with our good guidance regulations in 21 CFR 10.115, which provide for public comment at any time.

Consistent with § 7.50, all recalls monitored by FDA are included in an ''Enforcement Report'' once they are classified and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Recall data in the Enforcement Report can be accessed through the weekly report publication, the quick and advanced search functionalities, and an Application Programming Interface (API). Instructions for navigating the report, accessing and using the API, and definitions of the report contents are found at *https://www.fda.gov/safety/enforcement-reports/enforcement-report-information-and-definitions.*

In the **Federal Register** of January 8, 2021 (86 FR 1508), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Firm initiated recall; § 7.46	2,779	1	2,779	25	69,475
Termination of recall; § 7.55	2,095	1	2,095	10	20,950
Recall status reports; § 7.53	2,779	13	36,127	10	361,270
Total			41,001		451,695

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

A review of Agency data shows that 8,337 recalls were conducted during fiscal years 2017 through 2019, for an average of 2,779 recalls annually. We assume an average of 25 hours is needed to submit the requisite notification to FDA, for a total annual burden of 69,475 hours. Similarly, during the same period, 6,287 recalls were terminated,