| 21 CFR part or guidance | Topic | OMB Control No. |
|---|---|---|
| 807, subpart E | Premarket notification | 0910–0120 |
| 814, subparts A through E | Premarket approval | 0910–0231 |
| 814, subpart H | Humanitarian Device Exemption | 0910–0332 |
| 812 | Investigational Device Exemption | 0910–0078 |
| 820 | Quality System Regulation | 0910–0073 |
| 803 | Medical Device Reporting | 0910–0437 |
| ''De Novo Classification Process (Evaluation of Automatic Class III Designation)''. | De Novo classification process | 0910–0844 |
| ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''. | Q-submissions | 0910–0756 |
| 58 | Good Laboratory Practices | 0910–0119 |
| 312 | Investigational New Drug Application | 0910–0014 |
| 601 | Biologics License Application | 0910–0338 |

Dated: September 22, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–21234 Filed 9–24–20; 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.; Proposal To Withdraw Approval of Five Abbreviated New Drug Applications; Opportunity for a Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of five abbreviated new drug applications (ANDAs) and is announcing an opportunity for the ANDA holders to request a hearing on this proposal. The basis for the proposal is that the 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:** The ANDA holders may submit a request for a hearing by October 26, 2020. Submit all data, information, and analyses upon which the request for a hearing relies November 24, 2020. Submit electronic or written comments by November 24, 2020.

**ADDRESSES:** The request for a hearing may be submitted by the ANDA holders by either of the following methods:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including any attachments to the request for a hearing, will be posted to the docket unchanged.

*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.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request 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. The request for a hearing must include the Docket No. FDA–2020–N–1816 ''Lavipharm Laboratories, Inc., et al.; Proposal To Withdraw Approval of Five Abbreviated New Drug Applications; Opportunity for a Hearing.'' The request for a hearing will be placed in the docket and 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.

The ANDA holders may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions—To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. 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 any decisions on this matter. 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* or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law.

*Comments Submitted by Other Interested Parties:* For all comments submitted by other interested parties, 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–1816 for ''Lavipharm Laboratories, Inc., et al.; Proposal To Withdraw Approval of Five Abbreviated New Drug Applications; Opportunity for a Hearing.'' 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 § 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, 240–402–7500.

**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.

**SUPPLEMENTARY INFORMATION:** The holder of an approved ANDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved ANDA under §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). The holders of the approved ANDAs listed in table 1 have repeatedly failed to submit the required annual reports and have not responded to the Agency's request for submission of the reports.

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. We notified the holders of approved ANDAs in table 1 of the REMS requirement on September 28, 2017. The holders of the approved ANDAs listed in table 1 have failed to receive approval of a REMS for their products.

TABLE 1—APPROVED 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. |

Therefore, notice is given to the holders of the approved ANDAs listed in table 1 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e)(2) of the FD&C Act (21 U.S.C. 355(e)(2)), withdrawing approval of the ANDAs and all amendments and supplements thereto on the grounds that the ANDA holders have failed to submit reports required under §§ 314.81 and 314.98 and section 505(k) of the FD&C Act, and have failed to receive approval of a REMS for their products in accordance with section 505–1 of the FD&C Act.

In accordance with section 505(e) of the FD&C Act and 21 CFR 314.150(a) and (b)(1) and 21 CFR 314.200, the ANDA holders are hereby provided an opportunity for a hearing to show why the approval of the ANDAs identified above should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these ANDAs.

An ANDA holder who decides to seek a hearing must file the following: (1) a written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the ANDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the ANDAs, and the drug products may not thereafter be lawfully marketed or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing (§ 314.200(g)). If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing (§ 314.200(g)(1)).

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e)(2) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: September 16, 2020.

**Patrizia Cavazzoni,**

*Acting Director, Center for Drug Evaluation and Research.*

[FR Doc. 2020–21186 Filed 9–24–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Secretary's Advisory Committee on Human Research Protections

**AGENCY:** Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

**DATES:** The meeting will be held on Tuesday, October 20th, 2020, from 11:00 a.m. until 4:30 p.m., and Wednesday, October 21, 2020, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted at on the SACHRP website when this information becomes available.

**ADDRESSES:** This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

**FOR FURTHER INFORMATION CONTACT:** Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Tuesday, October 20, 2020, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair. The meeting will begin with presentation of recommendations on the interpretation of the public health surveillance exclusion, 45 CFR 46.102(l)(2) and 46.102(k). This will be followed by a panel review of ethical considerations regarding ''justice'' within 45 CFR 46, and how this concept may affect the actions of IRBs. The following day continues with a discussion of recommendations on risks to bystanders posed by the research setting. Other topics may be added; for the full and updated meeting agenda, see *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

The public will have an opportunity to comment to the SACHRP during the meeting's public comment session or by submitting written public comment. Persons who wish to provide public comment should review instructions at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html* and respond by midnight Wednesday, October 14, 2020, ET. Individuals submitting written statements as public comment should submit their comments to SACHRP at *SACHRP@hhs.gov.* Verbal comments will be limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by the SACHRP.

Dated: September 18, 2020.

**Julia G. Gorey,**

*Executive Director, SACHRP, Office for Human Research Protections.*

[FR Doc. 2020–21232 Filed 9–24–20; 8:45 am]

**BILLING CODE 4150–28–P**