2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* May 27, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for INPEFA (NDA 216203) was initially submitted on May 27, 2022.

3. *The date the application was approved:* May 26, 2023. FDA has verified the applicant's claim that NDA 216203 was approved on May 26, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17639 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3271]

Flamingo Pharmaceuticals Ltd.; Proposal To Withdraw Approval of Two 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 two abbreviated new drug applications (ANDAs) and is announcing an opportunity for the ANDA holder to request a hearing on this proposal. The basis for the proposal is that the ANDA holder has repeatedly failed to file required annual reports for those ANDAs.

DATES: The ANDA holder may submit a request for a hearing by September 9, 2024. Submit all data, information, and analyses upon which the request for a hearing relies October 7, 2024. Submit electronic or written comments by October 7, 2024.

ADDRESSES: The request for a hearing may be submitted by the ANDA holder 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–2024–N–3271 for ''Flamingo Pharmaceuticals Ltd.; Proposal To Withdraw Approval of Two 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. The ANDA holder 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. Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 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–2024–N–3271 for ''Flamingo Pharmaceuticals Ltd.; Proposal To Withdraw Approval of Two 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 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

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 holder 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.

TABLE 1—APPROVED ANDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	Holder
ANDA 207309	Metronidazole tablet, 250 milligrams (mg) and 500 mg	Flamingo Pharmaceuticals Ltd., U.S. Agent for Flamingo Pharmaceuticals Ltd., 1125 Gaither Rd., Rockville, MD 20850.
ANDA 207938	Piroxicam capsule, 10 mg and 20 mg	Do.

Therefore, under 21 CFR 314.150(b)(1) and § 314.200 (21 CFR 314.200), notice is given to the holder 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) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of the ANDAs and all amendments and supplements thereto on the grounds that the ANDA holder has failed to submit reports required under §§ 314.81 and 314.98.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the ANDA holder is hereby provided an opportunity for a hearing to show why the approval of the ANDAs listed previously 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 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 introduced 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. 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.

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) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: August 2, 2024.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 2024–17515 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3449]

Office of Pharmaceutical Quality Experiential Learning Site Visit Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Fiscal Year 2025 CDER Office of Pharmaceutical Quality (OPQ) Experiential Learning Site Visit Program (ELSVP). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to submit a site visit proposal to CDER's OPQ.

DATES: Starting October 1, 2024, FDA will accept requests to participate in the ELSVP program.

ADDRESSES: If your facility is interested in offering a site visit, submit either an electronic proposal to *CDEROPQSiteVisits@fda.hhs.gov* or a written proposal to Lyle Canida (see **FOR FURTHER INFORMATION CONTACT**). See the ''III. Site Selection'' and ''IV. Proposals for Participation'' sections of this document for potential priorities onsite selection criteria and how to submit a proposal to participate in the program.

FOR FURTHER INFORMATION CONTACT: Lyle Canida, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. M4522, Silver Spring, MD 20993–0002, 301–796–6825, email: *CDEROPQSiteVisits@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A critical part of the commitment by CDER to assure safe and effective high-quality drugs are available to the American public is gaining an understanding of all aspects of a drug's development and commercial lifecycle, including the variety of drug manufacturing operations. To support this commitment, CDER has initiated various training and development programs, including the FY2025 OPQ ELSVP. This site visit program is designed to offer experiential and firsthand learning opportunities that will provide OPQ staff with a better understanding of the pharmaceutical industry and its operations, as well as the challenges that may impact a drug's developmental program and commercial life cycle. The goal of these visits is to enhance OPQ staff exposure to the drug development and manufacturing processes in industry; therefore, a tour of pharmaceutical company facilities, including manufacturing and laboratory operations, is an integral part of the experience.

II. The Experiential Learning Site Visit Program (ELSVP)

In this site visit program, groups on average of no more than 15 OPQ staff—who have experience in a variety of educational backgrounds, supporting pharmaceutical quality assessment—will observe operations or important aspects of commercial manufacturing, pilot plants (if applicable), and testing over a 1- to 2-day period. To facilitate the learning process for OPQ staff, overview presentations by industry related to drug development, manufacturing, and testing may be included.

CDER encourages companies engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to respond.

OPQ staff participating in this program will benefit by gaining a better understanding of current industry practices, processes, and procedures. Participating sites will have an opportunity to showcase their technologies and their actual manufacturing and testing facilities.

Although observation of all aspects of drug development and production would be beneficial to OPQ staff, the following list identifies a number of areas of particular interest to its staff. The list is not intended to be exhaustive, mutually exclusive, or to limit industry response:

- Drug products:
  - Solutions, suspensions, emulsions, semisolids, and solids
  - Modified- and immediate-release formulations
  - Drug-device combination products regulated by CDER (*e.g.,* inhalation products, transdermal systems, implants intended for drug delivery, and pre-filled syringes)
- Active pharmaceutical ingredients manufactured by:
  - Chemical synthesis
  - Fermentation
  - Biotechnology
- Design, development, manufacturing, and controls:
  - Engineering controls for aseptic processes
  - Novel delivery technologies
  - Hot melt extrusion
  - Soft-gel encapsulation
  - Lyophilization
  - Blow-Fill-Seal packaging
  - Isolators
  - Spray-drying
  - Process analytical technology, measurement systems, and real-time release testing
- Advanced manufacturing technologies:
  - Continuous manufacturing
  - 3-dimensional printing
  - Nanotechnology
- Terminal sterilization:
  - Gamma irradiation
  - PET drug manufacturing and controls
  - Medical gas manufacturing and controls

III. Site Selection

Selection of potential facilities will be based on the priorities developed for OPQ staff training, the facility's current compliance status with FDA, and in consultation with the appropriate FDA district office. All travel expenses associated with this program will be the responsibility of CDER Offices; therefore, the number of sites selected will be based on the availability of funds and resources for the fiscal year. FDA will not provide financial compensation to the pharmaceutical site as part of this program.

IV. Proposals for Participation

Companies interested in offering a site visit or learning more about this site