

from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

IC-GREEN (indocyanine green for injection), 10 mg/vial, 25 mg/vial, 40 mg/vial, and 50 mg/vial, is the subject of NDA 011525, held by Akorn, Inc. IC-GREEN (indocyanine green for injection), 25 mg/vial and 50 mg/vial, became conditionally effective on February 2, 1959. IC-GREEN (indocyanine green for injection), 10 mg/vial and 40 mg/vial, became conditionally effective on March 20, 1967. NDA 011525 was included in the Drug Efficacy Study Implementation review, (35 FR 12231 (July 30, 1970); 42 FR 31495 (June 21, 1977)) and the application was approved on August 2, 1989. IC-GREEN (indocyanine green for injection) is indicated for determining cardiac output, hepatic function, and liver blood flow, and for ophthalmic angiography.

IC-GREEN (indocyanine green for injection), 10 mg/vial, 40 mg/vial, and 50 mg/vial, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Foley & Lardner LLP submitted a citizen petition dated May 3, 2018 (Docket No. FDA-2018-P-1734), under 21 CFR 10.30, requesting that the Agency determine whether IC-GREEN (indocyanine green for injection), 10 mg/vial, 40 mg/vial, and 50 mg/vial, was withdrawn from sale for reasons of safety or effectiveness. In 1987, IC-GREEN (indocyanine green for injection), 10 mg/vial and 40 mg/vial were discontinued from marketing. In 1996, Akorn, Inc. discontinued marketing IC-GREEN (indocyanine green for injection), 50mg/vial.

After considering the citizen petition and reviewing Agency records, and based on the information we have at this time, FDA has determined under

§ 314.161 that IC-GREEN (indocyanine green for injection), 10 mg/vial, 40 mg/vial, and 50 mg/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that IC-GREEN (indocyanine green for injection), 10 mg/vial, 40 mg/vial, and 50 mg/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of IC-GREEN (indocyanine green for injection), 10 mg/vial, 40 mg/vial, and 50 mg/vial from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list IC-GREEN (indocyanine green for injection), 10 mg/vial, 40 mg/vial, and 50 mg/vial, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to IC-GREEN (indocyanine green for injection), 10 mg/vial, 40 mg/vial, and 50 mg/vial, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-26975 Filed 12-12-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4416]

Allied Pharma, Inc., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of nine abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, *Trang.Tran@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 073079	Loperamide Hydrochloride (HCl) Oral Solution, 1 milligram (mg)/5 milliliters.	Allied Pharma, Inc., 20 Corrielle St., Fords, NJ 08863.
ANDA 076741	Ibuprofen Tablets USP, 100 mg	LNK International, Inc., 145 Ricefield Ln., Hauppauge, NY 11788.
ANDA 080210	Lidocaine Ointment, 5%	Belmora, LLC, 2231 Crystal Dr., #1000, Arlington, VA 22202.
ANDA 085497	Phendimetrazine Tartrate Tablets, 35 mg	Virtus Pharmaceuticals, LLC, 2050 Cabot Blvd. West, 2nd Floor, Langhorne, PA 19047.
ANDA 085695	Phendimetrazine Tartrate Capsules, 35 mg	Do.
ANDA 086365	Phendimetrazine Tartrate Tablets, 35 mg	Do.
ANDA 086399	Theolair (theophylline) Tablets, 125 mg and 250 mg	Medicis Pharmaceutical Corp., c/o Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 087378	Phendimetrazine Tartrate Extended-Release Capsules, 105 mg.	Virtus Pharmaceuticals, LLC.
ANDA 202030	Bromfenac Sodium Ophthalmic Solution, Equivalent to 0.09% Acid.	Amring Pharmaceuticals, Inc., 1235 Westlakes Dr., Suite 205, Berwyn, PA 19312.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 14, 2019. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on January 14, 2019, may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26947 Filed 12–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3984]

Data Integrity and Compliance With Drug CGMP: Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Data Integrity and Compliance With Drug CGMP: Questions and Answers.” The purpose of the guidance is to clarify the role of data integrity in current good manufacturing practice (CGMP) for drugs. (Unless otherwise noted, the term CGMP refers to CGMPs for drugs, including biologics.) The guidance has been developed in response to an increase in findings of data integrity lapses in recent inspections. FDA expects that all data be reliable and accurate. CGMP regulations and guidance allow for flexible and risk-based strategies to prevent and detect data integrity issues. Firms should implement meaningful and effective strategies to manage their data integrity risks based on their process understanding and knowledge management of technologies and business models.

DATES: The announcement of the guidance is published in the **Federal Register** on December 13, 2018.

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–2018–D–3984 for “Data Integrity and Compliance With Drug CGMP: Questions and Answers.” 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.