RPG CROSS-SITE EVALUATION ANNUALIZED BURDEN ESTIMATES—Continued

Data collection activity	Total number of respondents	Number of responses per respondent (each year)	Average burden hours per response (in hours)	Estimated total burden hours	Total annual burden hours
Partner survey	135	.33	0.42	56.3	18.8
Enrollment, client and service data					
Semi-annual progress reports	27	2	16.5	2,673	891
Case enrollment data	81	43	0.25	2,612.3	870.8
Case closure	81	43	0.017	174.2	58.1
Case closure—prenatal	81	33	0.017	133.7	44.6
Service log entries	162	2,288	0.03	37,065	12,355
Outcome and impact data					
Administrative Data:					
Obtain access to administrative data	27	1	42.6	3,450.6	1150.2
Report administrative data	27	2	144	23,328	7,776
Standardized instruments:					
Review and adopt reporting templates	27	.33	8	216	72
Data entry for standardized instruments	27	130	1.25	13,162.5	4,387.5
Review records and submit	27	2	25	4,050	1,350
Data entry for comparison study sites (22 grantees)	22	130	1.25	10,725	3,575
Estimated Total Burden Hours				97,827	32,609

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–27041 Filed 12–12–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–1734]

Determination That IC–GREEN (Indocyanine Green for Injection), 10 Milligrams/Vial, 40 Milligrams/Vial, and 50 Milligrams/Vial Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that IC–GREEN (indocyanine green for injection), 10 milligrams (mg)/vial, 40 mg/vial, and 50 mg/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for indocyanine green for injection, 10 mg/vial, 40 mg/vial, and 50 mg/vial if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Heather A. Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn

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]

BILLING CODE 4164–01–P

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.