TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS (CBER) [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 312.62(a); Investigator recordkeeping of the disposition of drugs	453	1	453	40	18,120
§ 312.62(b); Investigator recordkeeping of case histories of individuals	453	1	453	40	18,120
§ 312.160(a)(3); Records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests	111	1.40	155	*0.5	78
§ 312.160(c); Shipper records of alternative disposition of unused drugs	111	1.40	155	*0.5	78
Total					127,006

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

Because we have received an increased number of IND submissions since the last OMB approval of the information collection, we have increased our estimate of the associated burden accordingly.

Dated: February 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01962 Filed 2–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0163]

Hospira, Inc., et al.; Withdrawal of Approval of 12 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 12 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 14, 2019.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 065343	Epirubicin Hydrochloride (HCl) Injection USP, 10 milligrams (mg)/5 milliliters (mL), 50 mg/25 mL, 150 mg/75 mL, and 200 mg/100 mL.	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 070562	Flurazepam HCl Capsules USP, 15 mg	Pharmaceutical Basics, Inc., 301 South Cherokee St., Denver, CO 80223.
ANDA 070563	Flurazepam HCl Capsules USP, 30 mg	Do.
ANDA 071808	Flurazepam HCl Capsules USP, 15 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 071809	Flurazepam HCl Capsules USP, 30 mg	Do.
ANDA 076827	Vinorelbine Injection USP, Equivalent to 10 mg base/mL.	Hospira, Inc.
ANDA 077736	Polyethylene Glycol 3350 Powder for Oral Solution, 17 grams/scoopful.	Breckenridge Pharmaceutical, Inc., 6111 Broken Sound Parkway NW, Suite 170, Boca Raton, FL 33487.
ANDA 085763	Glutethimide Tablets, 500 mg	Chelsea Laboratories, Inc., 896 Orlando Ave., West Hampstead, NY 11552.
ANDA 085791	Pentobarbital Sodium Capsules, 100 mg	Do.
ANDA 087297	Glutethimide Tablets, 500 mg	Phoenix Pharmaceuticals, Inc., 111 Leuning St., South Hackensack, NJ 07606.
ANDA 088819	Aristocort A (triamcinolone acetonide) Cream, 0.1%	Astellas Pharma U.S., Inc., Three Parkway North, Deerfield, IL 60015.
ANDA 089459	Glutethimide Tablets, 500 mg	Halsey Drug Co., Inc.

Therefore, approval of the applications listed in the table and all amendments and supplements thereto, are hereby withdrawn as of March 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 March 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: February 7, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02032 Filed 2–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Contact Substance Notification Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by March 14, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0495. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Food Contact Substance Notification Program—21 CFR 170.101, 170.106, and 171.1

OMB Control Number 0910–0495—Extension

This information collection supports FDA regulations regarding Food Contact Substance Notification, as well as associated guidance and accompanying forms. Section 409(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the FD&C Act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the FD&C Act requires that the notification process be used for authorizing the marketing of food contact substances except when: (1) We determine that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the FD&C Act is necessary to provide adequate assurance of safety or (2) we and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the FD&C Act requires that a notification include: (1) Information on the identity and the intended use of the food contact substance and (2) the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) specify the information that a notification must contain and require that: (1) A food contact substance notification (FCN) includes Form FDA 3480 and (2) a notification for a food contact substance formulation includes Form FDA 3479. These forms serve to summarize pertinent information in the notification. The forms facilitate both preparation and review of notifications because the forms will serve to organize information necessary to support the safety of the use of the food contact substance. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Currently, interested persons transmit an FCN submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3480 whether it is submitted in electronic or paper format. We estimate that the amount of time for respondents to complete Form FDA 3480 will continue to be the same.

In addition to its required use with FCNs, Form FDA 3480 is recommended to be used to organize information within a Pre-notification Consultation or Master File submitted in support of an FCN according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to FDA, thus minimizing paperwork burden for food contact substance authorizations. We estimate that the amount of time for respondents to complete the Form FDA 3480 for these types of submissions is 0.5 hours.

FDA recommends using Form FDA 3480A for each submission of additional information (*i.e.,* amendment) to an FCN submission currently under Agency review. Form FDA 3480A helps the respondent organize the submission to focus on the information needed for FDA's safety review.

FDA's guidance documents entitled: (1) ''Preparation of Food Contact Notifications: Administrative,'' (2) ''Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations,'' and (3) ''Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations'' provide assistance to industry regarding the preparation of an FCN and a petition for a food contact substances (FCSs). FDA has also developed a draft guidance entitled, ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.'' Once finalized, the guidance will provide our current thinking on how to prepare an FCN for FDA review and evaluation of the safety of FCSs used in contact with infant formula and/or human milk. These guidances are available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/default.htm.*

Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to: (1) Establish that the proposed use of an indirect food additive is safe and (2) secure the publication of an indirect