

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section <sup>2</sup>	Number of recordkeepers	Number of records per recordkeeper <sup>3</sup>	Total annual records	Average burden per record-keeping <sup>4</sup>	Total hours
123.6(a)–(c); Prepare hazard analysis and HACCP plan	50	1	50	16 .....	800
123.6(c)(5); Undertake and prepare records of corrective actions.	15,000	4	60,000	0.30 (18 minutes).	18,000
123.8(a)(1) and (c); Reassess hazard analysis and HACCP plan.	15,000	1	15,000	4 .....	60,000
123.12(a)(2)(ii); Verify compliance of imports and prepare records of verification activities.	4,100	80	328,000	0.20 (12 minutes).	65,600
123.6(c)(7); Document monitoring of critical control points.	15,000	280	4,200,000	0.30 (18 minutes).	1,260,000
123.7(d); Undertake and prepare records of corrective actions due to a deviation from a critical limit.	6,000	4	24,000	0.10 (6 minutes)	2,400
123.8(d); Maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing.	15,000	47	705,000	0.10 (6 minutes)	70,500
123.11(c); Maintain sanitation control records .....	15,000	280	4,200,000	0.10 (6 minutes)	420,000
123.12(c); Maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123.	4,100	80	328,000	0.10 (6 minutes)	32,800
123.12(a)(2); Prepare new written verification procedures to verify compliance of imports.	41	1	41	4 .....	164
<b>Total</b> .....					1,930,264

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> These estimates include the information collection requirements in the following sections:

§ 123.16—Smoked Fish—process controls (see § 123.6(b));  
 § 123.28(a)—Source Controls—molluscan shellfish (see § 123.6(b));  
 § 123.28(c) and (d)—Records—molluscan shellfish (see § 123.6(c)(7)).

<sup>3</sup> Based on an estimated 280 working days per year.

<sup>4</sup> Estimated average time per 8-hour work day unless one-time response.

Based on a review of the information collection since our last OMB approval, we have made no adjustments to our burden estimate. We base this hour burden estimate on our experience with the application of HACCP principles in food processing. Further, the burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry. The hour burden of HACCP recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the size of the facility and complexity of the HACCP control scheme (*i.e.*, the number of products and the number of hazards controlled); the daily frequency that control points are monitored and values recorded; and also on the extent that data recording time and cost are minimized by the use of automated data logging technology. The burden estimate does not include burden hours for activities that are a usual and customary part of businesses' normal activities. For example, the

tagging and labeling of molluscan shellfish (§ 1240.60) is a customary and usual practice among seafood processors.

Dated: November 19, 2019.

**Lowell J. Schiller,**  
*Principal Associate Commissioner for Policy.*  
 [FR Doc. 2019–25857 Filed 11–27–19; 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 Six 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 six 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 December 30, 2019.

**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, 240–402–6980, *Martha.Nguyen@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 040806 .....	Mepivacaine Hydrochloride (HCl) Injection USP, 3%, 30 milligrams (mg)/milliliter (mL).	Hospira, Inc., 275 North Field Dr., Bldg. H, Lake Forest, IL 60045.

Application No.	Drug	Applicant
ANDA 077523 .....	Fluconazole for Oral Suspension, 50 mg/5 mL and 200 mg/5 mL.	IVAX Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 078772 .....	Epinephrine and Lidocaine HCl, 0.01 mg/mL; 2% and 0.02 mg/mL; 2%.	Hospira, Inc.
ANDA 079138 .....	Articaine HCl and Epinephrine Bitartrate Injection, 4%; EQ 0.017 mg base/1.7 mL, 4%; EQ 0.01 mg base/mL.	Do.
ANDA 204236 .....	Norethindrone Acetate Tablets, 5 mg .....	Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 204421 .....	Tramadol HCl Extended-Release Tablets, 100 mg, 200 mg, and 300 mg.	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 30, 2019. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. 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 December 30, 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: November 25, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-D-5255]

**Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products; Draft 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 draft guidance for industry entitled “Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products.” The purpose of this draft guidance is to provide recommendations to applicants

regarding whether and when comparative clinical immunogenicity studies may be needed to support licensure of proposed biosimilar and interchangeable recombinant human insulins, recombinant human insulin mix products, and recombinant insulin analog products that are intended for the treatment of patients with Type 1 or Type 2 diabetes mellitus.

**DATES:** Submit either electronic or written comments on the draft guidance by January 28, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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-2019-D-5255 for “Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products.” 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