TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
113.100 and 114.100	10,392	1	10,392	250	2,598,000

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

FDA bases its estimate of 10,392 recordkeepers in table 2 on its records of the number of registered firms, excluding firms that were inactive or out of business, yet still registered. To avoid double-counting, we have not included estimates for § 108.25(e), (g), and (h) because they merely cross-reference recordkeeping requirements contained in parts 113 and 114 and have been accounted for in the recordkeeping burden estimate. We estimate that 10,392 firms will expend approximately 250 hours per year to fully satisfy the recordkeeping requirements in parts 108, 113 and 114, for a total of 2,598,000 hours.

Finally, our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b) (21 CFR 114.80(b)) with an identifying code to permit lots to be traced after distribution. We seek OMB approval of the third party disclosure requirements in §§ 113.60(c) and 114.80(b). However, we have not included a separate table to report the estimated burden of these regulations. No burden has been estimated for the third party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: August 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19241 Filed 8–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1139]

Determination That DRIXORAL (Dexbrompheniramine Maleate; Pseudoephedrine Sulfate) Tablet and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6223, Silver Spring, MD 20993–0002, 301–796–5418, *Amy.Hopkins@fda.hhs.gov.*

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 approved 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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 013483	DRIXORAL (dexbrompheniramine maleate and pseudoephedrine sulfate) Tablet, Extended Release; Oral, 6 milligrams (mg)/120 mg.	MSD Consumer Care Inc., 556 Morris Ave., Summit, NJ 07901.
NDA 014685	AVENTYL (nortriptyline hydrochloride (HCl)) Solution; Oral, Equivalent to (EQ) 10 mg Base/5mL.	Ranbaxy Pharmaceuticals Inc., 600 College Rd. East, Princeton, NJ 08540.

Application No.	Drug	Applicant
NDA 016418	INDERAL (propranolol HCl) Tablet; Oral, 80 mg	Wyeth Pharmaceuticals Inc., C/O Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 016909	LIDEX (fluocinonide) Ointment; Topical 0.05%	County Line Pharmaceuticals, LLC, 13890 Bishop's Dr., Suite 410, Brookfield, WI 53005.
NDA 017373	LIDEX (fluocinonide) Gel; Topical 0.05%	.....Do.
NDA 020073	ROMAZICON (flumazenil) Injectable; Injection, 1 mg/10 milliliters (mL) (0.1 mg/mL); 0.5 mg/5 mL (0.1 mg/mL).	Hoffmann-La Roche Inc., C/O Genentech Inc., 1 DNA Way, South San Francisco, CA 94080–4990.
NDA 020229	LEUSTATIN (cladribine) Injectable; Injection, 1 mg/mL	Janssen Pharmaceuticals Inc., C/O Johnson and Johnson Pharmaceutical Research and Development LLC, 920 Rt. 202 South, P.O. Box 300, Raritan, NJ 08869.
NDA 020347	HYTRIN (terazosin HCl) Capsule; Oral, EQ 1 mg Base; EQ 2 mg Base; EQ 5 mg Base; EQ 10 mg Base.	Abbott Laboratories Pharmaceutical Products Division, Dept. 491 AP6B 1, Abbott Park, IL 60064.
NDA 020560	FOSAMAX (alendronate sodium) Tablet; Oral, EQ 5 mg Base; EQ 10 mg Base; EQ 35 mg Base; EQ 40 mg Base.	Merck and Co. Inc., 126 East Lincoln Ave., RY 33 212, P.O. Box 2000, Rahway, NJ 07065–0900.
NDA 020813	KLONOPIN (clonazepam) Tablet, Orally Disintegrating Tablet (ODT); Oral, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg.	Hoffmann-La Roche Inc., 340 Kingsland St., Nutley, NJ 07110.
NDA 021046	CELEXA (citalopram hydrobromide) Solution; Oral, EQ 10 mg Base/5 mL.	Forest Laboratories Inc., Harborside Financial Center, Plaza V, Suite 1900, Jersey City, NJ 07311.
NDA 022246	METOZOLV ODT (metoclopramide HCl) Tablet, ODT; Oral, EQ 10 mg Base.	Salix Pharmaceuticals Inc., 8510 Colonnade Center Dr., Raleigh, NC 27615.
NDA 050533	VIBRA–TABS (doxycycline hyclate) Tablet; Oral, EQ 100 mg Base.	Pfizer Laboratories Inc., 235 East 42nd St., New York, NY 10017.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19272 Filed 8–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0092]

Guidance for Industry on Immunogenicity Assessment for Therapeutic Protein Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled ''Immunogenicity Assessment for Therapeutic Protein Products.'' Therapeutic protein products may elicit immune responses, which may lead to serious or life-threatening adverse events for the patient or loss of efficacy of the product. This guidance is intended to assist manufacturers and clinical investigators in developing a risk-based approach in both the nonclinical and clinical phases of product development that will allow them to evaluate and reduce the likelihood that the immunogenicity of the product will cause harm to patients. This guidance finalizes the draft guidance issued in February 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or 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. 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.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amy Rosenberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 2238, Silver Spring, MD 20892, 240–402–9789; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Rockville, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Immunogenicity Assessment for Therapeutic Protein Products.'' The purpose of this guidance is to assist