

whose name appears on the label of a licensed biological product. In table 1, the number of respondents is based on the estimated number of manufacturers that are subject to those regulations or that submitted the required information to the Center for Biologics Evaluation and Research and Center for Drugs Evaluation and Research, FDA, in fiscal year (FY) 2016. Based on information obtained from the FDA's database system, there were 93 manufacturers of biological products. This number excludes those manufacturers who

produce Whole Blood, components of Whole Blood, or in-vitro diagnostic licensed products, because of the exemption under § 600.80(m). The total annual responses are based on the number of submissions received by FDA in FY 2016. There were an estimated 125,371 15-day Alert reports, 180,580 periodic reports, and 677 lot distribution reports submitted to FDA. The number of 15-day Alert reports for postmarketing studies under § 600.80(e) is included in the total number of 15-day Alert reports. FDA received 81

requests from 40 manufacturers for waivers under § 600.90 (including §§ 600.80(h)(2) and 600.81(b)(2)), of which 79 were granted. The hours per response are based on FDA experience. The burden hours required to complete the MedWatch Form (Form FDA 3500A) for § 600.80(c)(1), (e), and (f) are reported under OMB control number 0910-0291.

FDA estimates the burden of this collection of information as follows:

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

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
600.80(c)(1), 600.80(d), and 600.80(e); postmarketing 15-day Alert reports .....	93	1,348.07	125,371	1	125,371
600.82; notification of discontinuance or interruption in manufacturing .....	18	1.61	29	2	58
600.80(c)(2); periodic adverse experience reports .....	93	1,941.72	180,580	28	5,056,240
600.81 Distribution Reports .....	93	7.28	677	1	677
600.80(h)(2), 600.81(b)(2), and 600.90; waiver requests ...	40	2.03	81	1	81
<b>Total .....</b>					<b>5,182,427</b>

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

In table 2 the number of respondents is based on the number of manufacturers subject to those regulations. Based on information obtained from FDA's database system, there were 263 licensed manufacturers of biological products in FY 2016. However, the number of recordkeepers

listed for § 600.12(a) through (e) excluding (b)(2) is estimated to be 114. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under § 606.160 in OMB control number 0910-0116. The total annual records is based on the

annual average of lots released in FY 2016 (7,198), number of recalls made (575), and total number of adverse experience reports received (305,951) in FY 2016. The hours per record are based on FDA experience.

FDA estimates the burden of this recordkeeping as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours
600.12; <sup>2</sup> maintenance of records .....	114	63.14	7,198	32	230,336
600.12(b)(2); recall records .....	263	2.19	575	24	13,800
600.80(c)(1) and 600.80(k) .....	93	3,289.79	305,951	1	305,951
<b>Total .....</b>					<b>550,087</b>

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

<sup>2</sup> The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

The burden for this information collection has changed since the last OMB approval. Because of an increase in the number of AER reports we have received during the past 3 years, we have increased our reporting and recordkeeping burden estimates.

Dated: July 12, 2017.  
**Anna K. Abram,**  
*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2016-N-0002]**

**Hospira, Inc. et al.; Withdrawal of Approval of 44 New Drug Applications and 158 Abbreviated New Drug Applications; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of October 4, 2016 (81 FR 68427). The document announced the withdrawal of approval of 44 new drug applications and 158 abbreviated new drug applications (ANDAs) from multiple applicants, effective November 3, 2016. The document inadvertently announced withdrawal of approval for the following two ANDAs: ANDA 074123 for Pindolol Tablets, held by G&W Laboratories, Inc., 111 Coolidge St., South Plainfield, NJ 07080; and ANDA 080828 for Hydrocortisone Acetate Ophthalmic Ointment USP, held by Fera Pharmaceuticals LLC, 134 Birch Hill Rd., Locust Valley, NY 11560. FDA confirms that the approval of ANDAs 074123 and 080828 is still in effect.

**FOR FURTHER INFORMATION CONTACT:** Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Tuesday, October 4, 2016, appearing on page 68427 in FR Doc. 2016-23893, the following corrections are made:

1. On page 68429, in table 1, the entry for ANDA 074123 is removed.
2. On page 68431, in table 1, the entry for ANDA 080828 is removed.

Dated: July 12, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0017]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary National Retail Food Regulatory Program Standards

**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 August 17, 2017.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0621. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726.

**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.

#### Voluntary National Retail Food Regulatory Program Standards

*OMB Control Number 0910-0621—Extension*

The Voluntary National Retail Food Regulatory Program Standards (the Program Standards) define nine essential elements of an effective regulatory program for retail food establishments, establish basic quality control criteria for each element, and provide a means of recognition for the State, local, territorial, tribal and Federal regulatory programs that meet the Program Standards. The program elements addressed by the Program Standards are as follows: (1) Regulatory foundation; (2) trained regulatory staff; (3) inspection program based on Hazard Analysis and Critical Control Point (HACCP) principles; (4) uniform inspection program, (5) foodborne illness and food defense preparedness and response; (6) compliance and enforcement; (7) industry and community relations; (8) program support and resources; and (9) program assessment. Each standard includes a list of records needed to document conformance with the standard (referred to in the Program Standards document as “quality records”) and has one or more corresponding forms and worksheets to facilitate the collection of information needed to assess the retail

food regulatory program against that standard. The respondents are State, local, territorial, tribal, and potentially other Federal regulatory Agencies. Regulatory Agencies may use existing available records or may choose to develop and use alternate forms and worksheets that capture the same information.

In the course of their normal activities, State, local, territorial, tribal, and Federal regulatory Agencies already collect and keep on file many of the records needed as quality records to document compliance with each of the Program Standards. Although the detail and format in which this information is collected and recorded may vary by jurisdiction, records that are kept as a usual and customary part of normal Agency activities include inspection records, written quality assurance procedures, records of quality assurance checks, staff training certificates and other training records, a log or database of food-related illness or injury complaints, records of investigations resulting from such complaints, an inventory of inspection equipment, records of outside audits, and records of outreach efforts (e.g., meeting agendas and minutes, documentation of food safety education activities). No new recordkeeping burden is associated with these existing records, which are already a part of usual and customary program recordkeeping activities by State, local, territorial, tribal and Federal regulatory Agencies, and which can serve as quality records under the Program Standards.

In April 2016, the Conference for Food Protection (CFP) recommended that FDA make a change in Program Standard #4—Uniform Inspection Program, more specifically to change Program Standard #4’s Program Self-Assessment and Verification Audit Form. Once changes have been incorporated into the 2017 version, it will be available on FDA’s Web site.

With this change, in order to achieve conformance to Program Standard #4, jurisdictions must achieve an overall inspection program performance rating for 20 elements as opposed to 10 elements that were previously required. The previous 10 elements had several criteria under one program element. The change to 20 elements allows the Standard to clearly delineate out each criterion individually rather than having several criteria under one program element. This streamlines and clarifies the process in meeting the standard. As a result, the assessment review of each inspector’s work will now be required for three joint inspections as opposed to the previously required two.