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.

[FR Doc. 2017–15003 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

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 *oira_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. Mizrachi, 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.

State, local, territorial, tribal and Federal regulatory Agencies that enroll in the Program Standards and seek listing in the FDA National Registry are required to report to FDA on the completion of the following three management tasks outlined in the Program Standards: (1) Conducting a program self-assessment; (2) conducting a risk factor study of the regulated industry; and (3) obtaining an independent outside audit (verification audit). The results are reported on forms formerly known as Forms FDA 3519 and FDA 3520. Currently FDA is working to consolidate both Forms FDA 3519 ''FDA National Registry Report'' and FDA 3520 ''Permission to Publish in National Registry'' into one form thereby reducing the burden by 50 percent. The new Form FDA 3958 ''Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report'' will be provided in the Program Standards document, and will also be provided on FDA's Web site at: *https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm.* If a regulatory Agency follows all the recordkeeping recommendations in the individual standards and their sample worksheets, it will have all the information needed to complete the forms.

In the **Federal Register** of March 20, 2017 (82 FR 14369), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received four comments, two which duplicated each other. Therefore, FDA received three separate comments, two of which were PRA related and one which was not PRA-related and will not be addressed here.

(Comment 1) One commenter noted that achieving all of the standards under the existing program lasts only 2 years, and then a state regulatory program has to start all over again. The commenter indicated standards certification should last for 7 years, and then there would be more incentive to achieve some or all of the standards.

(Response 1) The purpose of the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) is to establish best practices for regulatory programs that license and inspect foodservice and retail food establishments. Jurisdictions are encouraged to use the Retail Program Standards to improve program management and to implement best practices that enhance the quality of public health services provided to stakeholders. Effective use of the Retail Program Standards will enable a jurisdiction to make lasting programmatic improvements to their retail food protection program. While meeting all nine standards is a significant accomplishment, the true intent is continual program improvement across all standards during varied time frames. There are general procedures for enrolling in the Retail Program Standards and maintaining active participation. Though timelines may vary depending on jurisdictional needs and priorities at any given time, the general administrative procedure is that within the first year of enrollment the jurisdiction will conduct a self-assessment using the criteria in the nine Retail Program Standards. As part of the continuous improvement process, jurisdictions review the self-assessment to determine program areas that need improvements and will provide the greatest health benefit. To maintain active participation in the Retail Program Standards and listing on the National Registry, the participating jurisdiction must conduct a self-assessment every 60 months. FDA works in conjunction with the Conference for Food Protection (CFP) in a process whereby representatives from the food industry, government, academia, consumer and professional organizations identify and address emerging problems of food safety in an open forum and formulate recommendations biennially to enhance the Retail Program Standards. These recommendations are then submitted to FDA for consideration to be incorporated into the newest edition of the FDA Food Code or the Retail Program Standards. Issues may be submitted by anyone who has an interest or concern about food safety. For an overview of the CFP please go to: *www.foodprotect.org.*

(Comment 2) Another commenter thanked the FDA for the opportunity to provide the comments on the proposed FDA Voluntary Standards. They stated that it was great to have these standards for health officials to do their absolute best for their community, and provided their comments to FDA on behalf of a trade quality assurance group.

(Response 2) FDA appreciates the continued support from the retail food industry for the Retail Program Standards. FDA works in conjunction with the CFP in a process whereby representatives from consumer and professional organizations, food industry, government, and academia identify and address emerging problems of food safety in an open forum and formulate recommendations. These recommendations are then submitted to FDA for consideration to be incorporated into the newest editions of the FDA Food Code or the Retail Program Standards. Issues may be submitted directly to CRP as there is a clear defined process and template for issue submittal. For an overview of the CFP and instructions on how to submit an issue, use the following link: *http://www.foodprotect.org/about/issue-submission/.*

Recordkeeping

FDA's recordkeeping burden estimate includes time required for a State, local, territorial, tribal, or Federal Agency to review the instructions in the Program Standards, compile information from existing sources, and create any records recommended in the Program Standards that are not already kept in the normal course of the Agency's usual and customary activities. Sample worksheets are provided to assist in this compilation. In estimating the time needed for the program self-assessment (Program Standards 1 through 8, shown in table 1), FDA considered responses from four State and three local jurisdictions that participated in an FDA Program Standards Pilot study. Table 2 shows the estimated recordkeeping burden for the completion of the baseline data collection, and table 3 shows the estimated recordkeeping burden for the verification audit.

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

TABLE 1—SELF-ASSESSMENT

Standard	Recordkeeping activity	Hours per record
No. 1: Regulatory Foundation	Self-Assessment: Completion of worksheet recording results of evaluations and comparison on worksheets [1].	16
No. 2: Trained Regulatory Staff	Self-Assessment: Completion of CFP Field Training Manual and Documentation of Successful Completion—Field Training Process; completion of summary worksheet of each employee training records [1 2].	19.3
No. 3: HACCP Principles	Self-Assessment: Completion of worksheet documentation [1]	4
No. 4: Uniform Inspection Program	Self-Assessment: Completion of worksheet documentation of jurisdiction's quality assurance procedures [1 2].	19
No. 5: Foodborne Illness Investigation	Self-Assessment: Completion of worksheet documentation [1]	5
No. 6: Compliance Enforcement	Self-Assessment: Selection and review of 20 to 70 establishment files at 25 minutes per file. Estimate is based on a mean number of 45. Completion of worksheet [1].	19
No. 7: Industry & Community Relations	Self-Assessment: Completion of worksheet [1]	2
No. 8: Program Support and Resources	Self-Assessment: Selection and review of establishment files [1]	8
Total		92.3

[1] Or comparable documentation.
[2] Estimates will vary depending on number of regulated food establishments and the number of inspectors employed by the jurisdiction.

TABLE 2—BASELINE DATA COLLECTION

Standard	Recordkeeping activity	Hours per record
No. 9: Program Assessment	Risk Factor Study and Intervention Strategy [1]	333

[1] Calculation based on mean sample size of 39 and average FDA inspection time for each establishment type. Estimates will vary depending on number of regulated food establishments within a jurisdiction and the number of inspectors employed by the jurisdiction.

TABLE 3—VERIFICATION AUDIT

Activity	Recordkeeping activity	Hours per record
Administrative Procedures	Verification Audit [1]	46.15

[1] We estimate that no more than 50% of time spent to complete self-assessment of all nine standards is spent completing verification audit worksheets. Time will be considerably less if less than nine standards require verification audits.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Recordkeeping for FDA Worksheets [2]	500	1	500	94.29	47,145

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

FDA bases its estimates of the number of recordkeepers and the hours per record on its experience with the Program Standards over the past 16 years. As of September 30, 2016, 711 jurisdictions were enrolled in the Program Standards. However, based upon the level of ongoing support provided by FDA to enrolled jurisdictions and the number of forms submitted annually, FDA estimates that no more than 500 jurisdictions actively participate in the Program Standards during any given year. There are approximately 3,000 jurisdictions in the United States and its territories that have retail food regulatory programs. Enrollment in the Program Standards is voluntary and, therefore, FDA does not expect all jurisdictions to participate.

FDA bases its estimate of the hours per record on the recordkeeping estimates for the management tasks of self-assessment, risk factor study, and verification audit (tables 1, 2, and 3) that enrolled jurisdictions must perform a total of 471.45 hours (92.3 + 333 + 46.15 = 471.45). Enrolled jurisdictions must conduct the work described in tables 1, 2, and 3 over a 5-year period. Therefore FDA estimates that, annually, 500 recordkeepers will spend 94.29 hours (471.45 ÷ 5 = 94.29) performing the required recordkeeping for a total of 47,145 hours as shown in table 4.

Reporting

Previously, FDA required regulatory jurisdictions that participate in the Program Standards to submit two forms annually: Form FDA 3519, ''FDA National Registry Report,'' and Form FDA 3520, ''Permission to Publish in National Registry.'' FDA created a new consolidated FDA Form 3958 that has four parts: Part 1 requires the name and address of the jurisdiction; name and contact information for the contact

person for this jurisdiction; the jurisdictions Web site address and if the jurisdiction is willing to serve as an auditor for another jurisdiction. Part 2 requires information about enrollment, whether this jurisdiction is a new enrollee and the date of enrollment; indication whether this jurisdiction would like to be removed from the jurisdiction listing; indication of updated findings to the self-assessment or verification audit. Part 3 requires information about self-assessment findings and verification audit findings; dates when self-assessment was completed; which standards have been met as determined by the self-assessment; which standards have been met as verified by a verification audit including the completion dates. Part 4 requires permission to publish information on FDA's Web site by checking the appropriate box(es) to indicate what information FDA may publish on the Web site.

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

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Submission of "Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report".	3,958	500	1	500	*0.1	50
Request for documentation of successful completion of staff training.	Conference for Food Protection Training Plan and Log.	500	3	1,500	*0.1	150
Total						200

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

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards. As explained previously, FDA estimates that no more than 500 regulatory jurisdictions will participate in the Program Standards in any given year. FDA estimates a total of 6 minutes annually for each enrolled jurisdiction to complete the form. FDA bases its estimate on the small number of data elements on the form and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3958 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour (or 6 minutes) per response for a total of 50 hours. In addition, FDA estimates that, annually, 500 regulatory jurisdictions will submit three requests for documentation of successful completion of staff training using the CFP Training Plan and Log for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour (or 6 minutes) per response for a total of 150 hours. The total reporting burden for this information collection is 200 hours.

Thus, the total hourly burden for this information collection is 47,345 hours (47,145 recordkeeping hours and 200 reporting hours).

Dated: July 12, 2017.

Anna K. Abram,

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

[FR Doc. 2017–14994 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3585]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Character-Space-Limited Online Prescription Drug Communications

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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title "Character-Space-Limited Online Prescription Drug Communications." Also include the FDA docket number found in brackets in the heading of this document.

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

Character Space-Limited Online Prescription Drug Communications

OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act. Under the FD&C Act and implementing