TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 089238	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Mikart, Inc., 1750 Chattahoochee Ave., Atlanta, GA 30318.
ANDA 089244	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
ANDA 089423	Amitriptyline HCl Tablets USP, 150 mg	Mutual Pharmaceutical Co., Inc.
ANDA 090849	Oxaliplatin for Injection USP, 50 mg/vial and 100 mg/vial	Sandoz Inc., 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director of Food and Drugs, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective November 12, 2015. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) 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: October 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25922 Filed 10–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3456]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Recordkeeping for Cosmetic Good Manufacturing Practices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies must publish a notice in the **Federal Register** concerning each proposed collection of information, including collections of information in current guidance documents, and allow 60 days for public comment. This notice invites comments on the recommended recordkeeping associated with our draft guidance entitled, ''Draft Guidance for Industry: Cosmetic Good Manufacturing Practices.'' Our draft guidance remains unchanged by this notice. We are publishing this notice in compliance with the PRA. This notice does not represent any new regulatory initiative.

DATES: Submit either electronic or written comments on the collection of information by December 14, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–3456 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Recordkeeping for Cosmetic Good Manufacturing Practices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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 must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other

applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including collections of information in current guidance documents, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Recommended Recordkeeping for Cosmetic Good Manufacturing Practices OMB Control Number 0910–NEW

The draft guidance, entitled ''Draft Guidance for Industry: Cosmetic Good Manufacturing Practices,'' (available at *http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm353046.htm#Raw*) provides guidance to industry and other stakeholders (*e.g.,* consumer interest groups, academia, other regulatory groups) on our current thinking concerning what constitutes Good Manufacturing Practices (GMPs) for cosmetics. It is intended to assist industry and other stakeholders in identifying the standards and issues that can affect the quality of cosmetic products. In addition, as part of an international harmonization effort with the International Cooperation on Cosmetic Regulations (ICCR), we agreed to consider the current International Organization for Standardization (ISO) standard for cosmetic GMPs (ISO 22716:2007) when developing the draft guidance. We have incorporated elements of ISO 22716, as appropriate, and that are consistent with our regulations.

Section 301 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331) prohibits the introduction, or delivery for introduction, into interstate commerce of cosmetics that are adulterated or misbranded. Manufacturers of cosmetics can reduce the risk of adulterating or misbranding cosmetics by following the GMP recommendations in the draft guidance.

The draft guidance recommends that manufacturers of cosmetics prepare written procedures and maintain records pertaining to: (1) Buildings and facilities; (2) equipment; (3) personnel; (4) raw materials; (5) production; (6) laboratory controls; (7) internal audits; and, (8) complaints, adverse events, and recalls.

We expect that manufacturers of cosmetics that choose to follow the recommendations of this Cosmetic GMP draft guidance would maintain records of their written procedures as well as their test methods or other appropriate verification procedures. It is also possible that manufacturers would obtain and maintain records of Certificates of Analysis, test results, or other appropriate verification procedures from their suppliers.

GMP is concerned with both manufacturing and quality control procedures. Manufacturers of cosmetics will use their written procedures and records as that part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use. Records would be compiled and retained at each manufacturing facility.

Description of Respondents: The respondents are manufacturers of cosmetic products.

Our draft guidance remains unchanged by this notice. We are publishing this notice in compliance with the PRA. This notice does not represent any new regulatory initiative.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME BURDEN TO ESTABLISH WRITTEN PROCEDURES [1]

Section of draft guidance	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Buildings and Facilities—Development of written procedures regarding maintaining the buildings and facilities used for manufacturing in a clean and orderly manner ...	607	1	607	1	607
Equipment—Development of written procedures regarding calibration and maintenance of equipment	607	1	607	36	21,852
Personnel—Development of written procedures regarding personnel, including documentation of education, training, and/or experience of personnel, and preventing microbial contamination from sick or infected personnel, and for hygienic practices	607	1	607	3.6	2,185

TABLE 1—ESTIMATED ONE-TIME BURDEN TO ESTABLISH WRITTEN PROCEDURES [1]—Continued

Section of draft guidance	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Raw Materials—Development of written procedures for identifying, storing, examining, testing, inventorying, handling, and controlling raw materials to ensure they conform to appropriate standards and specifications	607	1	607	10	6,070
Production—Development of written procedures regarding manufacturing operations	607	1	607	68	41,276
Laboratory Controls—Development of written procedures regarding laboratory controls	607	1	607	45	27,315
Internal Audit—Development of written procedures regarding internal audits	607	1	607	10.7	6,495
Complaints, Adverse Events, and Recalls [2]—Development of written procedures regarding product complaints and consumer adverse events	607	1	607	12	7,284
Complaints, Adverse Events, and Recalls [2]—Records regarding returned product	607	1	607	6	3,642
Total					116,726

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] To avoid double-counting, the burden hour analysis in table 1 does not include burden hours already accounted for in the information collection approved under OMB control number 0910–0249 for our recall regulations (21 CFR part 7).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR RECORDS MAINTENANCE [1]

Section of draft guidance	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Buildings and Facilities—Records regarding maintaining the buildings and facilities used for manufacturing in a clean and orderly manner	1,518	1	1,518	2	3,036
Equipment—Records regarding calibration and maintenance of equipment	1,518	1	1,518	3.3	5,009
Personnel—Records regarding personnel, including documentation of education, training and/or experience of personnel, and preventing microbial contamination from sick or infected personnel, and for hygienic practices	1,518	1	1,518	41.1	62,390
Raw Materials—Records regarding identifying, storing, examining, testing, inventorying, handling, and controlling raw materials to ensure they conform to appropriate standards and specifications	1,518	1	1,518	231.5	351,417
Production—Records regarding manufacturing operations	1,518	1	1,518	7.7	11,689
Laboratory Controls—Records regarding laboratory controls	1,518	1	1,518	1.2	1,822
Internal Audit—Records of internal audits	1,518	1	1,518	231.5	351,417
Complaints, Adverse Events, and Recalls [2]—Records regarding product complaints and consumer adverse events	1,518	1	1,518	60.3	91,535
Complaints, Adverse Events, and Recalls [2]—Records regarding returned product	1,518	1	1,518	5.1	7,742
Total					886,057

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] To avoid double-counting, the burden hour analysis in table 1 does not include burden hours already accounted for in the information collection approved under OMB control number 0910–0249 for our recall regulations (21 CFR part 7).

In table 1 we list the one-time burdens associated with establishing written procedures. In table 2 we list the annual burdens associated with recordkeeping. We base our estimates of the number of recordkeepers reported in column 2 of tables 1 and 2 on data available to us, our knowledge of and experience with the cosmetics industry, and our communications with industry, as well as our estimate of the number of recordkeepers subject to cosmetic labeling regulations, published in the **Federal Register** of June 25, 2014 (79 FR 36069). We estimate there are 1,518 cosmetic product establishments in the United States (79 FR 36069 at 36070). We estimate that 20 percent of these (304 establishments) are large businesses and 80 percent (1,214 establishments) are small businesses. We further estimate that large businesses are likely to have established written procedures and that about half of the small businesses (607 establishments) may not have established written procedures. Thus, for purposes of this analysis, we assume that these 607 establishments will undertake to establish written procedures recommended by the draft guidance, when it is finalized, as reported in table 1, column 2. We

further assume that the 1,518 cosmetic product establishments may not maintain all of the records recommended by the draft guidance. Thus, for purposes of this analysis, we assume that 1,518 establishments will keep the records recommended by the draft guidance, when it is finalized, as reported in table 2, column 2. We further assume that if multiple products are produced in the same facility, the written procedures and recordkeeping will be shared among the multiple products.

We base our estimates of the number of records per recordkeeper and the average burden per recordkeeping reported in columns 3 and 5 of tables 1 and 2 on our experience with good manufacturing practices used to control the identity and composition of food and dietary supplements and to limit contaminants and prevent adulteration, as well as our estimate of the burden of similar recordkeeping activities described in the dietary supplement final rule published in the **Federal Register** of June 25, 2007 (72 FR 34752 at 34916) (the June 25, 2007, final rule), that established, in part 111 (21 CFR part 111), the minimum good manufacturing practices necessary for dietary supplements. For the recordkeeping recommendations listed in table 2, the recordkeeping occasions consist of frequent brief entries of dates, temperatures, monitoring results, or documentation that specific actions were taken. Information might be recorded a few times a day, week, or month. Because the records burden involves frequent brief entries, we did not attempt to estimate the actual number of recordkeeping occasions for these activities. We entered one as the default for the number of records per recordkeeper and we calculated the average burden per recordkeeping in column 5 based on the reported burden of similar provisions estimated in the June 25, 2007, final rule, averaged across the 1,460 firms covered by that final rule.

The estimates for the recordkeeping burdens presented here are averages. We anticipate that the time spent to develop written procedures and recordkeeping would vary based on the type of cosmetic product manufactured. The estimated burdens for developing recordkeeping includes record maintenance, periodically reviewing records to determine if they may be discarded, and any associated documentation for that activity.

This draft guidance also refers to previously approved collections of information found in our regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3521). The collections of information in our recall regulations in 21 CFR part 7 have been approved under OMB control number 0910–0249. The collection of information in 21 CFR 70.25, which requires that color additives subject to certification be labeled with the lot number assigned by the Color Certification Branch, has been approved under OMB control number 0910–0016.

Dated: October 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25957 Filed 10–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3543]

Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Information in Direct-to-Consumer Television Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled ''Quantitative Information in Direct-to-Consumer Television Advertisements.'' The objective of this research is to test consumers' understanding of quantitative information about prescription drugs in DTC television advertisements (ads).

DATES: Submit either electronic or written comments on the collection of information by December 14, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–3543 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Information in Direct-to-Consumer Television Advertisements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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