TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Public Health Service Act section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1701(a)(4)	308	3	924	0.17	157

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

Based on the history of the PHN program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: December 8, 2010.

Leslie Kux,

Acting Assistant, Commissioner for Policy.

[FR Doc. 2010–31387 Filed 12–14–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0623]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Cosmetic Registration Program

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the Agency's Voluntary Cosmetic Registration Program (VCRP).

DATES: Submit either electronic or written comments on the collection of information by February 14, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850. 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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 each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's 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.

Voluntary Cosmetic Registration Program—21 CFR Parts 710 and 720 (OMB Control Number 0910–0027)—Revision

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides FDA with the authority to regulate cosmetic products in the United States. Cosmetic products that are adulterated under section 601 of the FD&C Act (21 U.S.C. 361) or misbranded under section 602 of the FD&C Act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, the Agency has developed the VCRP.

In 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the Agency on Form FDA 2511 entitled "Registration of Cosmetic Product Establishment." The term "Form FDA 2511" refers to both the paper and electronic versions of the form. The electronic version of Form FDA 2511 is available on FDA's VCRP Web site at *http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm.* FDA's online registration system, intended to make it easier to participate in the VCRP, was made available industrywide on December 1, 2005. The Agency strongly encourages electronic registration of Form FDA 2511 because it is faster and more convenient. A registering facility will receive confirmation of electronic registration, including a registration number, by e-mail, usually within 7 business days. The online system also allows for amendments to past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA places the registration information in a computer database and uses the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the

information for estimating the size of the cosmetic industry and for conducting onsite establishment inspections. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

In part 720 (21 CFR part 720), FDA requests that firms that manufacture, pack, or distribute cosmetics file with the Agency an ingredient statement for each of their products. Ingredient statements for new submissions (§§ 720.1 through 720.4) are reported on Form FDA 2512, "Cosmetic Product Ingredient Statement," and on Form FDA 2512a, a continuation form. Amendments to product formulations (§ 720.6) also are reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514, "Notice of Discontinuance of Commercial Distribution of Cosmetic Product Formulation" (§§ 720.3 and 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA's online filing system is available on FDA's VCRP Web site at *http://wcms.fda.gov/FDAgov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm.* The online filing system contains the electronic versions of Forms FDA 2512, 2512a, and 2514, which are collectively found within the electronic version of Form FDA 2512. The Agency strongly encourages electronic filing of Form FDA 2512 because it is faster and more convenient. A filer will receive confirmation of electronic filing by e-mail.

FDA places cosmetic product filing information in a computer database and uses the information for evaluation of cosmetic products currently on the market. Because filing of cosmetic product formulations is not mandatory, voluntary filings provide FDA with the best information available about cosmetic product ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. The information assists FDA scientists in evaluating reports of alleged injuries and adverse reactions from the use of cosmetics. The information also is used in defining and planning analytical and toxicological studies pertaining to cosmetics.

Information from the database is releasable to the public under FDA compliance with the Freedom of Information Act. FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section or part	Form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Part 710 (registrations)	FDA 2511 [2]	135	1	135	0.2	27
720.1 through 720.4 (new submissions).	FDA 2512 [3]	141	31	4,371	0.33	1,442
720.6 (amendments)	FDA 2512	109	7	763	0.17	130
720.6 (notices of discontinuance)	FDA 2512	55	41	2,255	0.1	226
720.8 (requests for confidentiality)		1	1	1	2.0	2.0
Total						1,827

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

[2] The term "Form FDA 2511" refers to both the paper Forms FDA 2511 and electronic Form FDA 2511 in the electronic system known as the Voluntary Cosmetic Registration Program, which is available at *http://wcms.fda.gov/FDAgov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm.*

[3] The term "Form FDA 2512" refers to the paper Forms FDA 2512, 2512a, and 2514 and electronic Form FDA 2512 in the electronic system known as the Voluntary Cosmetic Registration Program, which is available at *http://wcms.fda.gov/FDAgov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm.*

FDA bases its estimate of the number of responses on submissions received from fiscal years 2005 to 2007. FDA bases its estimate of the hours per response upon information from cosmetic industry personnel and FDA experience entering data submitted on paper Forms 2511, 2512, 2512a, and 2514. FDA estimates that, annually, 135 establishments that manufacture or package cosmetic products will each submit 1 registration on Form FDA 2511, for a total of 135 annual responses. Each submission is estimated to take 0.2 hour per response for a total of 27 hours. FDA estimates that, annually, 141 firms that manufacture, pack, or distribute cosmetics will file 31 ingredient statements for new submissions on Forms FDA 2512 and FDA 2512a, for a total of 4,371 annual responses. Each submission is estimated to take 0.33 hour per response for a total of 1,442.43 hours, rounded to 1,442. FDA estimates that, annually, 109 firms that manufacture, pack, or distribute cosmetics will file 7 amendments to product formulations on Forms FDA 2512 and FDA 2512a, for a total of 763 annual responses. Each submission is estimated to take 0.17 hour per response for a total of 129.71 hours, rounded to 130. FDA estimates that, annually, 55 firms that manufacture, pack, or distribute cosmetics will file 41 notices of discontinuance on Form FDA 2514, for a total of 2,255 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 225.50 hours, rounded to 226. FDA estimates that, annually, one firm will file one request for confidentiality. Each such request is estimated to take 2 hours to prepare for a total of 2.0 hours. Thus, the total estimated hour burden for this information collection is 1,827 hours.

This is a revision request in which the burden hours for the information collection request (ICR) under OMB control number 0910–0030, "Cosmetic Product Voluntary Reporting Program" are being consolidated under the ICR assigned OMB control number 0910–0027, "Voluntary Registration of Cosmetic Product Establishments," which expires February 28, 2011. The revised ICR for 0910–0027 has been renamed "Voluntary Cosmetic Registration Program." Upon approval of this revision request, the ICR for 0910–0030 will be discontinued.

Dated: December 9, 2010.

Leslie Kux,

Acting Assistant, Commissioner for Policy.

[FR Doc. 2010–31386 Filed 12–14–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0616]

Draft Guidance for Industry on Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination." This guidance is intended to assist sponsors in the codevelopment of two or more novel (not previously marketed) drugs to be used in combination to treat a disease or condition. This guidance provides recommendations and advice on how to address certain scientific and regulatory issues that will arise during codevelopment. The guidance is not intended to apply to development of fixed-dose combinations of already marketed drugs or to development of a single new investigational drug to be used in combination with an approved drug or drugs. The guidance is also not intended to apply to vaccines, gene or cellular therapies, blood products, or medical devices.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 14, 2011.

ADDRESSES: Submit written requests for single copies of the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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: Colleen Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm 4216, Silver Spring, MD 20993–0002, 301–796–1114.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination." The guidance is intended to assist sponsors interested in developing two or more novel (not previously marketed) drugs to be used in combination. Recent scientific advances have increased our understanding of the pathophysiological processes that underlie many complex diseases, such as cancer, cardiovascular disease, and infectious diseases. This increased understanding has provided further impetus for new therapeutic approaches that rely primarily or exclusively on combinations of drugs directed at multiple therapeutic targets to improve treatment response and minimize development of resistance. In settings in which combination therapy provides significant therapeutic advantages, there is growing interest in the development of combinations of investigational drugs not previously developed for any purpose.

Because the existing developmental and regulatory paradigm focuses primarily on assessment of the effectiveness and safety of a single new investigational drug acting alone, or in combination with an approved drug, FDA believes guidance is needed to assist sponsors in the codevelopment of two or more unmarketed drugs. This guidance is intended to describe a high-level, generally applicable approach to codevelopment of two or more unmarketed drugs. It describes the criteria for determining when codevelopment is an appropriate option, makes recommendations about nonclinical and clinical development strategies, and addresses certain regulatory process issues. The guidance does not apply to vaccines, gene or cellular therapies, or blood products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on companion diagnostic devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: December 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31426 Filed 12–14–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0618]

Statement of Organization, Functions and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has reorganized its Center for Tobacco Products (CTP) by establishing two new offices: Office of Health Communication and Education and the Office of Compliance and Enforcement. In addition, CTP has made improvements to the current offices' functional statements. This organizational change is intended to fill the gaps in the current CTP structure and clarify major responsibilities designed for long-term success in administering the Family Smoking Prevention and Tobacco Control Act.