Telephone: (202) 401–2344. e-mail: *Lhodge@acf.dhhs.gov.*

VIII. Other Information

Training and Technical Assistance: All potential ANA applicants are eligible to receive T&TA in the SEDS, Language, or Environmental program areas. Prospective applicants should check ANA's web site for training and technical assistance dates and locations, or contact the ANA Help Desk at 1–877–922–9262. Due to the new application and program additions and modifications, ANA strongly encourages all prospective applicants to participate in free pre-application training.

Dated: Dated February 20, 2004.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans.

[FR Doc. 04–4304 Filed 2–26–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0063]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Registration of Cosmetic Product Establishments

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 voluntary registration of cosmetic product establishments with FDA.

DATES: Submit written or electronic comments on the collection of information by April 27, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* 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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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 Registration of Cosmetic Product Establishments—21 CFR Part 710 (OMB Control Number 0910–0027)—Extension

The Federal Food, Drug, and Cosmetic Act (the act) provides FDA with the responsibility for assuring consumers that cosmetic products in the United States are safe and properly labeled. Cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA has developed the Voluntary Cosmetic Registration Program (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.'' Form FDA 2511 is available on FDA's VCRP Web site at *http://www.cfsan.fda.gov/~dms/cos-regn.html.*

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.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	15	1	15	0.4	6

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

The VCRP was suspended during fiscal year (FY) 1998 due to a lack of budgetary funding and was reinstated at the beginning of FY 1999. The estimated hour burden for this information collection is 30 percent of the previous level reported in 2000. In general, the larger cosmetic companies have resumed participating in the VCRP, whereas the smaller companies are lagging.

Dated: February 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4339 Filed 2–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004C–0078]

Cryovac North America; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cryovac North America has filed a petition proposing that the color additive regulations be amended to provide for the safe use of synthetic iron oxide as a color additive in or on cooked meat products.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS 265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3076.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 4C0276) has been filed by Cryovac North America, c/o Keller and Heckman LLP, 1001 G St. NW., Suite 500 West, Washington, DC 20001. The petition proposes to amend the color additive regulations in 21 CFR part 73 to provide for the safe use of synthetic iron oxide as a color additive in or on cooked meat products.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: February 5, 2004.

George H. Pauli,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 04–4340 Filed 2–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0478]

Draft Guidance on Marketed Unapproved Drugs; Compliance Policy Guide; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until April 27, 2004, the comment period on the draft guidance for industry entitled ''Marketing Unapproved Drugs; Compliance Policy Guide.'' The agency announced the availability of this draft guidance in the **Federal Register** of October 23, 2003 (68 FR 60702). The initial comment period closed December 22, 2003. The agency is taking this action to provide interested persons additional time to review the draft guidance and submit comments.

DATES: Submit written or electronic comments on the draft guidance by April 27, 2004. General comments on agency guidance documents are welcome at anytime.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sakineh H. Walther, Center for Drug Evaluation and Research (HFD–318), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8964.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 23, 2003 (68 FR 60702), FDA published the draft guidance for industry entitled ''Marketing Unapproved Drugs; Compliance Policy Guide.'' This draft guidance describes how FDA intends to exercise its enforcement discretion with regard to drugs marketed in the United States that do not have required FDA approval for marketing. This document will, when finalized, supersede section 440.100 entitled ''Marketed New Drugs Without Approved NDAs or ANDAs'' (CPG 7132c.02) of the Compliance Policy Guide. It applies to any new drug required to have FDA approval for marketing, including new drugs covered by the over-the-counter review. The initial comment period closed on December 22, 2003, but to provide interested persons additional time to review the draft guidance and submit comments, the agency is reopening the comment period for an additional 60 days, until April 27, 2004.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination 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 copies of this draft guidance for industry at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 20, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4310 Filed 2–26–04; 8:45 am]

BILLING CODE 4160–01–S