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]

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Draft Guidance on Marketed Unapproved Drugs; Compliance Policy Guide; Availability; Reopening of Comment Period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

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