

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Draft Guidance on Marketed Unapproved Drugs; Compliance Policy Guide; Availability; Reopening of Comment Period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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0027]

Draft Guidance for Industry on Time and Extent Applications; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of February 10, 2004 (69 FR 6309). The document announced the availability of a draft guidance for industry entitled "Time and Extent Applications." The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Joyce A. Strong, Office of the Commissioner (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 04-2729, appearing on page 6309 in the **Federal Register** of Tuesday, February 10, 2004, the following correction is made:

1. On page 6309, the docket number in the heading of the document is corrected to read "[Docket No. 2004D-0027]."

Dated: February 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-4311 Filed 2-26-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Review of Programs for Genomic Application (PGAs).

Date: March 4, 2004.

Time: 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Arthur N Freed, PhD, Review Branch, Room 7186, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892, (301) 435-0280.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Review of Career Enhancement Awards (K18s).

Date: March 11, 2004.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert B Moore, PhD, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7178, MSC 7924, Bethesda, MD 20892, (301) 435-0725.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 20, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-4333 Filed 2-26-04; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel.

Date: April 7, 2004.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Office of Program Operations, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel.

Date: April 7, 2004.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Office of Program Operations, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: February 20, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-4330 Filed 2-26-04; 8:45 am]

BILLING CODE 4140-01-M