



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

1837 Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

OCT 30 2000

Brian B. Hoffman, MD
Professor of Medicine and Molecular Pharmacology
Stanford University School of Medicine
3801 Miranda Avenue
Medical Service 111
Palo Alto, California 94304

Dear Dr. Hoffman:

Thank you for writing regarding the inclusion of phenylpropanolamine in our recent meeting on the safety of dietary supplements containing ephedrine alkaloids.

The Federal Register notice from the Food and Drug Administration (FDA) (copy enclosed) that extended the comment period on this subject to September 30, 2000, included a paragraph seeking comment on a report on phenylpropanolamine. This particular notice referenced our meeting, but the meeting purpose was not changed to accommodate this new request by FDA. Several speakers did reference the report, however, and their remarks are contained in the transcript which you can access at www.4woman.gov or as instructed in the Federal Register.

The most appropriate place for you to voice your concern is to the FDA docket. I will forward your letter and a copy of this response to FDA's Dockets Management Branch. If you have further questions, you may contact Jenny Butler at (301) 827-6880.

Again, thank you for writing. I encourage you to obtain the meeting transcript so you can more fully understand the context in which presenters addressed the phenylpropanolamine issue.

Sincerely,

Wanda K. Jones, Dr.P.H.
Deputy Assistant Secretary for Health
(Women's Health)

Enclosure

00N-1200
81N-0022

76N-052N

ANS 1

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Kindergarten Teachers	800	1	0.50	400

Annualized Totals:

Year 1, 5892
 Year 2, 4113
 Year 3, 4528
 Year 4, 1600

Estimated Total Annual Burden Hours: 4033.

Note: The 4033 Total Annual Burden Hours is based on an average of 2000, 2001, 2002, and 2003 estimated burden hours.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of the this publication.

Dated: July 24, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00-19259 Filed 7-28-00; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 98F-1022]

COPA Distributors, Inc.; Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 8C0263) proposing that the color additive regulations be amended to provide for the safe use of pyrogallol and ferrous sulfate as a color additive in hair dyes.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3078.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of December 8, 1998 (63 FR 67695), FDA announced that a color additive petition (CAP 8C0263) had been filed by COPA Distributors, Inc., c/o Research It!, Inc., 116 Huckleberry Lane, Henderson, NV 89014. The petition proposed to amend the color additive regulations in Part 73—*Listing of Color Additives Exempt From Certification* (21 CFR part 73) to provide for the safe use of pyrogallol and ferrous sulfate as a color additive in hair dyes. COPA Distributors, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: June 29, 2000.

Alan M. Rulis,

Director, Office of Premarket Approval,
 Center for Food Safety and Applied Nutrition.

[FR Doc. 00-19175 Filed 7-28-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 00N-1200]

Dietary Supplements Containing Ephedrine Alkaloids; 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 from August 10 to September 30, 2000, the comment period for a notice that published in the Federal Register of April 3, 2000 (65 FR 17510), that announced the availability of new adverse event reports (AER's) and related information concerning dietary supplements containing ephedrine alkaloids. This action is being taken in conjunction with a separate Federal Register notice by the U.S. Department of Health and Human Services' Office of Women's Health (OWH), which is part of the U.S. Public Health Service (PHS), announcing that it will hold a public meeting on August 8 and 9, 2000, to discuss available information about the safety of dietary supplements containing ephedrine alkaloids. FDA is also giving notice of the availability of a report on phenylpropanolamine and risk of hemorrhagic stroke.

DATES: Submit written comments on the notice of availability by September 30, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: FDADockets@oc.fda.gov, or http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6733.

SUPPLEMENTARY INFORMATION:

I. Reopening the Comment Period

In the Federal Register of April 3, 2000 (65 FR 17510), FDA published a notice announcing a new public docket that makes available new AER's and related information concerning dietary supplements containing ephedrine alkaloids. The Federal Register notice (65 FR 17510) also announced FDA's intent to participate in a public forum to address safety information on such products. Interested persons were given until May 18, 2000, to submit written comments on the April 3, 2000, Federal Register notice to FDA's public docket (Docket No. 00N-1200). FDA later extended this comment period until July 3, 2000 (65 FR 32113, May 22, 2000).

In a separate Federal Register notice (65 FR 43021, July 12, 2000), OWH announced that it will convene a public meeting to discuss available information about the safety of dietary supplements containing ephedrine alkaloids. These products are promoted for uses such as weight loss, body building, and increased energy. This meeting will afford all interested persons an opportunity to provide focused comment in a manner that will assist PHS in understanding the benefits and risks associated with dietary supplements containing ephedrine alkaloids. The PHS public meeting is scheduled for August 8 and 9, 2000. For more information, refer to the July 12, 2000, Federal Register notice, or visit the OWH Internet site (The National Women's Health Information Center) at <http://www.4woman.gov/owh/public>.

In light of this public meeting, FDA is reopening the comment period for the April 3, 2000, notice from August 10 to September 30, 2000. The information and comments generated from the PHS public meeting, along with the information in the public docket (Docket No. 00N-1200), will be considered by FDA in assessing the safety of dietary supplements containing ephedrine alkaloids that are promoted for uses such as weight loss, body building, and increased energy.

The agency has added a report entitled "Phenylpropanolamine and Risk of Stroke: Final Report of the Hemorrhagic Stroke Project" to the public docket (Docket No. 00N-1200). The agency seeks written comment on this report and its relevancy to an assessment of the safety of dietary supplements containing ephedrine alkaloids.

II. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments from August

10 to September 30, 2000. You may also send comments to the Dockets Management Branch via the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>, or e-mail: FDADockets@oc.fda.gov. Comments are to be identified with the docket number found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

You may request a transcript of the PHS meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting after August 25, 2000, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, as well as on the Internet at <http://www.fda.gov>.

Dated: July 25, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-19286 Filed 7-26-00; 4:06 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10014]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB).

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or

other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. Due to an unanticipated event, we are requesting an emergency review because the data collection and the associated time frame is required by a Congressionally mandated demonstration project (Informatics, Telemedicine, and Education Demonstration Project). This project is defined under Section 4207 of the Balanced Budget Act of 1997 which specifies an overall time frame of four years. In order to meet this overall time frame study the pilot phase for the recruitment of subjects should begin in late August 2000, with the full implementation of the recruitment phase beginning on October 1, 2000. Subject recruitment, in turn, will involve data collection involved in the Paper Reduction Act submission.

HCFA is requesting OMB review and approval of this collection by 8/7/2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by 8/3/2000. During this 180-day period, we will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection

Request: New Collection;

Title of Information Collection: Informatics, Telemedicine, and Education Demonstration Project;

Form No.: HCFA-10014 (OMB# 0938-NEW);

Use: Section 4207 of the Balanced Budget Act of 1997 mandated HCFA to conduct a demonstration project to evaluate the effectiveness of advanced computer and telecommunications technology ("telemedicine") to manage the care of people with diabetes. HCFA issued a request for proposals and, after review of the responses, selected a consortium led by Columbia University to conduct this project.