the SUPPLEMENTARY INFORMATION section for electronic access to agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Rita Hassall, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the withdrawal of 20 individual product labeling guidances. A list of FDA's Center for Drug Evaluation and Research (CDER) guidances (the Comprehensive List) can be found on the Internet on the CDER guidance page at *http://www.fda.gov/cder/guidance/index.htm*, and many of the guidances on the Comprehensive List are posted on the CDER guidance page (old draft guidances have not been posted). This withdrawal of labeling guidances is in addition to the withdrawal of 53 individual product labeling guidances announced in the **Federal Register** of July 5, 2002 (67 FR 44857).

The labeling guidances being withdrawn were intended to provide sponsors of abbreviated new drug applications (ANDAs) with product specific templates for package insert labeling that could be submitted to the Office of Generic Drugs (OGD). Because package insert labeling for innovator products changes frequently, it is difficult to keep the guidances updated; and because these labeling guidances are out of date, they are being withdrawn.

In May 2000, the agency issued a guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' This guidance provides information on how to access current package insert labeling on OGD's Labeling Review Branch Internet site at *http://www.fda.gov/cder/ogd/rld/labeling_review_branch.htm*.

The withdrawal of product-specific labeling guidances is part of a long-term effort in OGD to review guidance documents on the development of generic drug products with the goal of identifying documents that need to be revised, reformatted, or withdrawn because they are no longer current.

CDER is withdrawing the following labeling guidances:

Chlordiazepoxide Hydrochloride Capsules—January 1, 1988

Clorazepate Dipotassium Capsules/Tablets—March 1, 1993

Cyproheptadine Hydrochloride Tablets/Syrup—December 1, 1986

Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%—November 2, 1998

Ergoloid Mesylate Tablets—January 1, 1988

Hydroxyzine Hydrochloride Injection—December 1, 1989

Isoetharine Inhalation Solution—March 1, 1989

Meclofenamate Sodium Capsules—July 1, 1992

Naphazoline Hydrochloride Ophthalmic Solution—March 1, 1989

Niacin Tablets—July 1, 1992

Phendimetrazine Tartrate Capsules/Tablets, and Extended-Release Capsules—February 1, 1991

Phentermine Hydrochloride Capsules/Tablets—August 1, 1988

Promethazine Hydrochloride Tablets—March 1, 1990

Propantheline Bromide Tablets—August 1, 1988

Pyridoxine Hydrochloride Injection—June 1, 1984

Quinidine Sulfate Capsules USP—October 1, 1995

Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets—February 1, 1992

Theophylline Immediate Release Oral Dosage Forms—February 1, 1995

Thiamine Hydrochloride Injection—February 1, 1988

Vitamin A Capsules—February 1, 1992

II. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain guidance documents at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 25, 2002.

Margaret M. Dotzel

Assistant Commissioner for Policy.

[FR Doc. 02–30481 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0503]

Compliance Policy Guide: ''Filth from Insects, Rodents, and Other Pests in Food''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled ''Filth from Insects, Rodents, and Other Pests in Food.'' The purpose of this CPG is to revise and clarify existing guidance on the interpretation of filth in foods within the context of current science. The CPG provides guidance to FDA components as well as to the industry.

DATES: Submit written or electronic comments concerning the CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG ''Filth from Insects, Rodents, and Other Pests in Food'' to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or FAX your request to 301–827–0482. *See* the SUPPLEMENTARY INFORMATION section for electronic access to the document.

Submit written comments on the CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT:

Technical Questions Concerning Filth in Foods: Alan R. Olsen, Microanalytical Branch (HFS–315), Office of Plant, Dairy Foods, and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1962, FAX 301–436–2644.

Questions Concerning Regulatory Actions: Nina Adler, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0417, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of December 18, 2001 (66 FR 65214), FDA announced the availability of a draft CPG entitled ''Filth from Insects, Rodents, and Other Pests in Food.'' FDA has finalized the draft CPG after receiving no comments on the document. The CPG revises and clarifies existing guidance on foods that contain filth from insects, rodents, and other pests to reflect recent advances in science. The purpose of this CPG is to provide clear policy to FDA's field and headquarters staff with regard to filth from insects, rodents, and other pests in foods. It also contains information that may be useful to the regulated industry and to the public.

The CPG supersedes the current CPG and represents the agency's current thinking on the subject. 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 an approach satisfies the requirements of applicable statutes or regulations.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

II. Comments

Interested persons may submit to the Docket Management Branch (*see* **ADDRESSES**) written or electronic comments on the CPG entitled ''Filth from Insects, Rodents, and Other Pests in Food'' at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the CPG and received comments may be seen in the Dockets Management Branch (*see* **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the CPG also may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the CPG and may be accessed at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: November 4, 2002.

John M. Taylor,

Senior Associate Commissioner for Regulatory Affairs.

[FR Doc. 02–30403 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1378]

Draft Guidance for Industry on Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients.'' FDA has considered evidence that suggests that topically applied cosmetic products containing alpha hydroxy acids (AHAs) may increase the sensitivity of skin to the sun while the products are used and for up to a week after use is stopped and that this increased skin sensitivity to the sun may increase the possibility of sunburn. The purpose of this draft guidance is to educate manufacturers to help ensure that their labeling for AHA-containing cosmetic products is not false or misleading. The draft guidance suggests content for a labeling statement for AHA-containing cosmetic products. This action was prompted by a citizen petition filed by the Cosmetic, Toiletry, and Fragrance Association (CTFA), which requested that FDA issue a regulation establishing sun alert labeling on AHA-containing products.

DATES: Submit written or electronic comments by January 31, 2003, to ensure their adequate consideration in preparation of the final document. Comments on this draft guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Cosmetics and Colors (HFS–100), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Submit electronic comments on the draft guidance to *http://www.fda.gov/dockets/ecomments*. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Julie N. Barrows, Center for Food Safety and Applied Nutrition (HFS–105), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3412.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients.'' This draft guidance explains FDA's suggested labeling of topically applied cosmetic products that contain AHAs to alert consumers of the need to use sun protection when using these products. The guidance will educate manufacturers to help ensure that their labeling for AHA-containing cosmetic products is not false or misleading under 21 U.S.C. 362(a) and 321(n).

AHAs are organic acids with a hydroxyl group on the carbon adjacent to the carboxylic acid group. The predominant AHAs present in cosmetic products are glycolic acid and lactic acid. Other AHAs that are found in cosmetic products include citric acid, -hydroxyoctanoic acid, and -hydroxydecanoic acid (Ref. 1). Since the early 1990s, there has been a proliferation of AHA-containing cosmetic and salon products (Ref. 2). AHAs have been formulated into skin products, make-up, hair products, nail products, bath products, colognes, and suntan preparations. Most AHA-containing products are ''leave on'' products that are intended for daily use on the skin or mucous membrane or are ''discontinuous use'' products that are intended to be applied to the skin for a short period of time (*e.g.*, less than an hour) followed by thorough rinsing. Salon products are usually discontinuous use products.

FDA received a total of 107 adverse dermatologic experience reports for AHA-containing skin care products between 1992 and 2000, with the maximum number (32) in 1994 (Ref. 2). The reported adverse experiences include: Burning (43), dermatitis or rash (33), swelling (26), pigmentary changes (15), blisters or welts (13), skin peeling (12), itching (12), irritation or tenderness (6), chemical burns (6), and increased sunburn (3).

Starting in 1994, CTFA's Cosmetic Ingredient Review (CIR) Expert Panel, FDA's AHA Review Committee, and FDA reviewed the safety of topically applied AHAs in cosmetic products