finding, under section 306(b)(2)(B)(i)(II) and (a)(2) of the act (21 U.S.C. 335a(b)(2)(B)(i)(II) and (a)(2)) that Ms. Charpentier was convicted of a felony under Federal law for conspiring to make false statements in matters within the jurisdiction of a Government agency, FDA, and that Ms. Charpentier's conduct undermined the process for the regulation of drugs.

The certified letter also informed Ms. Charpentier that her request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also informed Ms. Charpentier that if it conclusively appeared from the face of the information and factual analyses in her request for a hearing that there was no genuine and substantial issue of fact that precluded the order of debarment, FDA would enter summary judgment against her and deny her request for a hearing.

In a letter dated May 28, 2002, Ms. Charpentier requested a hearing on the proposal and indicated she would submit further information to justify a hearing. Ms. Charpentier filed a letter dated July 1, 2002, in which she again requested an opportunity for a hearing. In her request for a hearing, Ms. Charpentier discusses her motives for her illegal conduct, her embarrassment and her financial problems resulting from her conviction. Such matters do not create a basis for a hearing because hearings will not be granted on mere allegations, denials, or general descriptions of positions and contentions, nor on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)(2) and (b)(3)).

II. Denial of Hearing

In her requests for a hearing, Ms. Charpentier does not present any arguments or information to show why she should not be debarred. Ms. Charpentier acknowledges that the agency is aware of the facts and states that she submitted the July 1, 2002, request for a hearing to set forth ''some of the circumstances that led up to this unfortunate situation.'' Ms. Charpentier's explanation of the facts leading to her conviction does not raise a genuine and substantial issue of fact requiring a hearing.

Ms. Charpentier is subject to permissive debarment based on: (1) FDA's findings that she was convicted of a Federal felony that undermined the regulatory process (section 306(b)(2)(B)(i)(II) and (a)(2) of the act)) and (2) FDA's determination that debarment is appropriate in this case based on a consideration of applicable factors set forth in section 306(c)(3) of the act. After FDA finds that the statutory criteria for permissive debarment has been met, the only relevant issue is whether Ms. Charpentier was, in fact, convicted as alleged in the proposal to debar. Ms. Charpentier does not dispute that she pled guilty to one Federal felony count for actions that undermined the regulation of drug products. In fact, in her letter of July 1, 2002, Ms. Charpentier: (1) Acknowledges wrongdoing, stating that she made a ''big mistake''; (2) expresses her remorse; and (3) offers an apology for her illegal conduct. Section 306(l)(1)(B) of the act includes in its definition of a conviction, a guilty plea. The facts underlying Ms. Charpentier's conviction have been established by her conviction and, therefore, are not at issue. In her July 1, 2002, letter, Ms. Charpentier's discusses the motives resulting in her conviction, her remorse, her apology, and her statements indicating that she will not again participate in illegal activity. This information does not justify a hearing. Although such information may be considered in determining whether to grant special termination of debarment under section 306(d)(4)(C) of the act, this information does not raise a factual dispute regarding Ms. Charpentier's conviction, but rather supports it. Thus, FDA finds that Ms. Charpentier has failed to identify any genuine and substantial issue of fact requiring a hearing. Accordingly, FDA denies Ms. Charpentier's request for a hearing.

III. Findings and Order

Therefore, the Deputy Commissioner, under section 306(b) of the act and under authority delegated to him (21 CFR 5.10), finds that Ms. Laverne M. Charpentier has been convicted of a felony under Federal law for conspiracy to make false statements to a Government agency, and that Ms. Charpentier's conduct undermined the process for the regulation of drugs.

As a result of the foregoing findings, Ms. Laverne M. Charpentier is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective December 2, 2002 (sections 306 (c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Ms. Charpentier, in any capacity, during her period of debarment, will be subject to civil money penalties. If Ms. Charpentier, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Charpentier during her period of debarment.

Any application by Ms. Charpentier for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 00N–1527 and sent to the Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 2002.

Lester M. Crawford,

Deputy Commissioner.

[FR Doc. 02–30482 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0451]

Withdrawal of 20 Guidances on Individual Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of 20 individual product labeling guidances. The guidances are being withdrawn because they are out of date and of little use to the generic drug industry. The agency has developed other guidance and resources to assist the industry in obtaining up-to-date labeling for reference listed drugs.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments 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*. See

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: