evidenced by a legible U.S. Postal Service dated postmark or a legible dated receipt from a commercial carrier, unless it arrives too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. An application not received on time will not be considered for review and will be returned to the applicant. (The applicant should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.) Do not send the application to the CSR, NIH. The application must be submitted via mail or hand delivered as stated above. FDA is unable to receive the application electronically. The applicant is advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH for its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01). All ''General Instructions'' and ''Specific Instructions'' in the application kit must be followed with the exception of the receipt dates and the mailing label address.

The face page of the application must reflect the request for application number, RFA-FDA CFSAN–02–3.

Data and information included in the application, if identified by the applicant as trade secret or confidential commercial information will be given treatment as such to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–001.

Dated: June 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16817 Filed 7–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0253]

Withdrawal of 53 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 53 individual product labeling guidances. The guidances are being withdrawn because they are outdated and of little use to the generic drug industry. The agency has developed other guidance and resources to assist 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. Submit written requests for the guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling'' to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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: FDA is announcing the withdrawal of 53 individual product labeling guidances. These labeling guidances, currently available on the Center for Drug Evaluation and Research (CDER) guidance list, were intended to provide sponsors of abbreviated new drug applications (ANDAs) with product specific templates for package insert labeling that would be accepted by the Office of Generic Drugs (OGD). Package insert labeling for innovator products changes frequently, and it is difficult to keep the guidances updated. The guidances are being withdrawn because they are outdated and of limited use to the generic drug industry.

The withdrawal of these 53 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 (64 FR 36886, July 8, 1999).

The following guidances are withdrawn:

Guidance	Date of Issuance
Acetaminophen, Aspirin and Codeine Phosphate Tablets and Acetaminophen, Aspirin and Codeine Phosphate Capsules	Revised December 1993
Acetaminophen and Codeine Phosphate Oral Solution and Oral Suspension	Revised December 1993
Alprazolam Tablets	Revised August 1996
Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP	September 1997
Amlodipine Besylate Tablets	September 1997
Astemizole Tablets	September 1997
Atenolol Tablets	August 1997
Butalbital, Acetaminophen and Caffeine Tablets USP or Butalbital, Acetaminophen and Caffeine Capsules USP	September 1997
Butalbital, Acetaminophen, Caffeine and Hydrocodone Bitartrate Tablets	September 1997
Butorphanol Tartrate Injection USP	Revised October 1992
Captopril and Hydrochlorothiazide Tablets USP	April 1995
Captopril Tablets	February 1995
Carbidopa and Levodopa Tablets USP	Revised February 1992
Cimetidine Hydrochloride Injection	September 1995
Cimetidine Tablets USP	Revised September 1995
Cisapride Oral Suspension	September 1997
Cisapride Tablets	September 1997
Clindamycin Phosphate Injection, USP	Revised September 1998
Diclofenac Sodium Delayed-Release Tablets	Revised February 1995
Diltiazem Hydrochloride Extended-Release Capsules	Revised September 1995

Guidance	Date of Issuance
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP	April 1995
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP	April 1995
Fludeoxyglucose F18 Injection	January 1997
Flurbiprofen Tablets USP	Revised January 1994
Fluvoxamine Maleate Tablets	September 1997
Gentamicin Sulfate Ophthalmic Solution USP and Gentamicin Sulfate Ophthalmic Ointment USP	Revised April 1992
Heparin Sodium Injection USP	Revised March 1991
Hydrocodone Bitartrate and Acetaminophen Tablets USP	Revised April 1994
Indomethacin Capsules USP	Revised September 1995
Itraconazole Capsules	September 1998
Leucovorin Calcium for Injection	July 1996
Leucovorin Calcium Tablets USP	July 1996
Medroxyprogesterone Acetate Tablets USP	Revised September 1998
Metaproternol Sulfate Inhalation Solution USP	Revised May 1992
Metaproterenol Sulfate Syrup USP	Revised May 1992
Metaproterenol Sulfate Tablets USP	Revised May 1992
Metoclopramide Tablets USP and Metoclopramide Oral Solution USP	Revised February 1995
Naproxen Sodium Tablets USP	September 1997
Naproxen Tablets USP	September 1997
Paclitaxel Injection	September 1997
Quinidine Sulfate Tablets, USP	October 1995
Ranitidine Tablets USP	Revised November 1993
Risperidone Oral Solution	September 1997
Risperidone Tablets	September 1997
Sulfacetamide Sodium Ophthalmic Solution USP and Sulfacetamide Sodium Ophthalmic Ointment USP	Revised August 1993
Sulfacetamide Sodium and Prednisolone Acetate	Revised January 1995
Sulfamethoxazole and Trimethoprim Tablets USP and Sulfamethoxazole and Trimethoprim Oral Suspension USP	Revised August 1993
Theophylline	Revised February 1995
Theophylline Intravenous Dosage Forms	September 1995
Tobramycin Sulfate Injection USP	Revised May 1993
Venlafaxine Hydrochloride Tablets	October 1997
Verapamil Hydrochloride Tablets	October 1991
Zolpidem Tartrate Tablets	September 1997

In May 2000, the agency issued the 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 Web site at http://www.fda.gov/cder/ogd/rld/labeling_review_branch.htm.

Interested persons may submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain CDER guidance documents at http://www.fda.gov/cder/guidance/index.htm.

Dated: June 24, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16796 Filed 7–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1454]

Guidance for Industry on Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation.'' This document provides guidance for industry on the chemistry, manufacturing, and controls documentation that should be submitted in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for nasal spray and inhalation solution, suspension, and spray drug products intended for local and/or systemic effect. The guidance also provides recommendations on labeling.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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 the guidance document.

FOR FURTHER INFORMATION CONTACT: Guirag Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION: