compounded drug product may be eligible for the previously noted exemptions if it is compounded under either of two conditions. These conditions are as follows: (1) The State in which the drug is compounded has entered into an MOU with FDA ''which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State''; or (2) the State in which the drug is compounded has not entered into such an MOU and a licensed pharmacist, pharmacy, or physician ''distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.'' Section 503A(b)(3)(B) of the act directs FDA to develop, in consultation with the NABP, a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i) of the act.

FDA consulted with the NABP concerning this standard MOU, and the agency is now making available for public comment a draft standard MOU regarding the interstate distribution of compounded drug products. The draft standard MOU sets forth the responsibilities of State agencies and FDA with respect to the following: (1) Investigating and responding to complaints relating to compounded drug products distributed outside of a State, and (2) responding to the distribution of inordinate amounts of compounded drug products in interstate commerce.

FDA invites comments from interested persons on the draft standard MOU on the interstate distribution of compounded drug products. The agency is providing a 60-day comment period and is establishing a docket for the receipt of comments. As stated in its guidance for industry entitled ''Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act'' (see 63 FR 64723, November 23, 1998), after considering any comments on the draft standard MOU submitted to this docket, FDA will finalize the standard MOU and make it available for signature by individual State agencies. Until at least 90 days after the standard MOU is finalized and made available to the States for their consideration and signature, the agency intends to exercise its enforcement discretion and normally will not take regulatory action regarding the requirement in section 503A(b)(3)(B)(ii) of the act, which states that a licensed pharmacist, pharmacy, or physician may not distribute or cause to be distributed in interstate commerce compounded drug products constituting more than 5 percent of the total prescription orders dispensed or distributed.

Interested persons may, on or before March 22, 1999, submit to the Dockets Management Branch (address above) written comments on the draft standard MOU. 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. The draft standard MOU and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1366 Filed 1–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1169]

Draft Guidance for Industry on Content and Format for Geriatric Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Content and Format for Geriatric Labeling.'' FDA established the ''Geriatric use'' subsection in the labeling for human prescription drug products in a final rule. The Geriatric use subsection includes biological drug products in order to provide for the inclusion of information pertinent to the appropriate use of drugs in the elderly (persons aged 65 and over). This draft guidance is intended to provide industry with information on submitting geriatric labeling for human prescription drug and biological products, including who should submit revised labeling, the implementation schedule, a description of the regulation and optional standard language in proposed labeling, the content and format for geriatric labeling, and the applicability of user fees to geriatric labeling supplements.

DATES: Written comments may be submitted on the draft guidance by March 22, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of ''Content and Format for Geriatric Labeling'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request. 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.

FOR FURTHER INFORMATION CONTACT:

Diana M. Hernandez, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Content and Format for Geriatric Labeling.'' This draft guidance has been developed in response to a final rule that published in the **Federal Register** of August 27, 1997 (62 FR 45313), establishing, in the ''Precautions'' section of prescription drug labeling, a subsection on the use of drugs in elderly or geriatric patients (aged 65 years or over) (§ 201.57(f)(10) (21 CFR 201.57(f)(10))). The geriatric labeling regulation recognizes the special concerns associated with the geriatric use of prescription drugs and acknowledges the need to communicate important information so that drugs can be used safely and effectively in older patients. The medical community has become increasingly aware that prescription drugs can produce effects in the elderly that are significantly different from those produced in younger patients. Geriatric labeling information is of increasing importance because of the growing proportion of the population that is over 65 years of age

and the significant use of medications by this age group.

This draft guidance discusses which application holders are responsible for submitting revised labeling and summarizes the implementation schedule for submitting geriatric labeling. The geriatric labeling regulation includes six paragraphs (§ 201.57(f)(10)(i) through (f)(10)(vi)) that outline various options for statements in the ''Geriatric use'' subsection, based on the type of information available and the interpretation of that information. The draft guidance summarizes the requirements of § 201.57(f)(10)(i) through (f)(10)(vi), and it provides detailed guidance on the submission of this information. In addition, the content and format for geriatric labeling, as well as the applicability of user fees to geriatric labeling supplements, are discussed in detail in the draft guidance document.

This draft guidance is a level 1 draft guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the content and format of geriatric labeling. 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 approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1363 Filed 1–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1267]

Draft Guidance for Industry on NDA's: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''NDA's: Impurities in Drug Substances.'' This draft document recommends that applicants submitting new drug applications (NDA's) and holders of supporting Type II drug master files (DMF's) for drug substances not considered new drug substances refer to the guidance for industry on reporting drug substance impurities in the International Conference on Harmonisation (ICH) guidance document entitled ''Q3A Impurities in New Drug Substances.''

DATES: Written comments on the draft guidance document may be submitted by April 21, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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.

FOR FURTHER INFORMATION CONTACT: Eric P. Duffy, Office of New Drug Chemistry, Office of Pharmaceutical Science, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7310.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''NDA's: Impurities in Drug Substances.'' Although ICH guidance document entitled ''Q3A Impurities in New Drug Substances,'' which was published in the **Federal Register** on January 4, 1996 (61 FR 371), provided guidance to industry on the reporting, identification, and qualification of impurities in new drug substances produced by chemical syntheses, FDA believes that the guidance provided in ICH Q3A also applies to drug substances produced by chemical syntheses that are not considered new drug substances. FDA recommends that applicants preparing NDA's and holders preparing Type II DMF's refer to the reporting information contained in that document.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on reporting impurities in drug substances for certain NDA's and DMF's. 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 approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1364 Filed 1–20–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–263]

Agency Information Collection Activities: Proposed Collection; Comment Request

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