presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 28, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–24997 Filed 10–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1562]

Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications; 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 ''Cancer Drug and Biological Products—Clinical Data in Marketing Applications.'' This guidance provides recommendations for sponsors designing clinical trials to demonstrate the safety and efficacy of cancer treatments on the collection of data that can be submitted to support marketing claims in new drug applications (NDAs), biologics license applications (BLAs), or applications for supplemental indications.

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, or the Office of Communications, 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 the office in processing your requests. A faxed copy of this guidance can also be obtained by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit written comments on the document 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:

Grant A. Williams, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5740, or

Patricia Keegan, Center for Biologics Evaluation and Research (HFM–573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Cancer Drug and Biological Products—Clinical Data in Marketing Applications.'' This guidance provides general principles for data collection and submission for sponsors of investigational new drug applications, NDAs, BLAs, or supplemental applications for new indications. The guidance is intended to enable sponsors to more effectively create plans to record and report the data from controlled trials that form the clinical basis for approval of anticancer drug and biological products

In the **Federal Register** of November 9, 2000 (65 FR 67389), FDA announced the availability of a draft version of this guidance. After FDA considered public comments on the draft guidance, the agency determined that revision of the draft guidance was necessary. The final guidance notes that tumor images usually are not submitted as part of the marketing application, but this should be clarified at presubmission meetings with FDA. The final guidance also states that information on drug dosing should be collected from all patients rather than from a sample of patients, as suggested in the draft guidance. Collecting dosing information in all patients allows a full assessment of the adequacy of dosing in both the investigational arm and the control arm of the submitted studies.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on clinical data in marketing applications for cancer drug or biologic products. 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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above). Two copies of written 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. The 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: September 28, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24946 Filed 10–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1169]

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 guidance for industry entitled ''Content and Format for Geriatric Labeling.'' FDA established the ''Geriatric use'' subsection in the labeling for human prescription drug and biological products to provide pertinent information about the appropriate use of drugs in the elderly (persons aged 65 and over). This 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 the proposed labeling, the content and format for geriatric labeling supplements, and the applicability of user fees to geriatric labeling supplements.

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

ADDRESSES: Submit written requests for single copies of this guidance 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 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: Mary E. Ortuzar, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6740; or Toni Stifano, Center for Biologics Evaluation and Research (HFM–600), 1401 Rockville Pike,Rockville, MD 20852, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Content and Format for Geriatric Labeling.'' This 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))). A draft guidance by the same name was made available for comment by a notice published in the **Federal Register** of January 21, 1999 (64 FR 3302). This guidance incorporates minor revisions based on comments the agency received on the draft guidance. The final guidance makes clear that the application holder is responsible for submitting a supplement to request the omission of the ''Geriatric use'' subsection or to request an alternative statement and for providing the reasons supporting the request.

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 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 guidance summarizes the requirements of § 201.57(f)(10)(i) through (f)(10)(vi) and provides detailed guidance on the submission of this information. In addition, the content and format for geriatric labeling supplements, as well as the applicability of user fees to geriatric labeling supplements, are discussed in detail in the guidance document.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance 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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the 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 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm.

Dated: September 28, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24945 Filed 10–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This Notice is also available on the internet at the following websites: *http://workplace.samhsa.gov; http://www.drugfreeworkplace.gov;* and *http://www.health.org/workplace.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl,