DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Registration and Listing Grassroots Meeting for Medical Device Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: Registration and Listing Grassroots Meeting for Medical Device Manufacturers. The topic to be discussed is FDA's intention to propose changes to the current medical device registration and listing process. This meeting is being conducted to provide a forum in which FDA can obtain industry views on changes to the device registration and listing system that FDA is currently considering. The changes being considered are aimed at streamlining the collection of registration and listing data, improving the accuracy and quality of the data in the system, and decreasing the time it takes manufacturers to register their establishments and list their devices, while ultimately reducing FDA's cost of maintaining the registration and listing system.

DATES: The meeting will be held on May 25, 1999, 8:30 a.m. to 12 noon; registration will begin at 7:30 a.m.

ADDRESSES: The meeting will be held at 9200 Corporate Blvd., rm. 20B, Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Bryan H. Benesch, Food and Drug Administration, Center for Devices and Radiological Health, Office of Health and Industry Programs (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 ext. 131, (FAX) 301–443–8810, (e-mail) ''BHB@CDRH.FDA.GOV''.

Those persons interested in attending the meeting should fax or e-mail their registration including name, title, firm name, address, telephone, and fax number. There is no charge to attend this meeting, but advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Bryan H. Benesch at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Over the past one and a half years, FDA has reviewed the entire registration and listing process to determine if the process can be made more efficient and accurate. This was one of many reengineering efforts conducted by the Center for Devices and Radiological Health (CDRH). This reengineering effort has resulted in a number of suggestions aimed at improving the registration and listing process for both FDA and industry. This meeting will help FDA obtain the medical device industry perspective on the changes under consideration and suggestions for additional changes. FDA has announced two meetings on the same subject to be held April 20, 1999, in California (64 FR 12813, March 15, 1999).

Some of the changes that FDA is currently considering include the following:

(1) Require industry submission of registration and listing information through the World Wide Web (WEB). What are the advantages and disadvantages to industry, and how would industry be affected if WEB submissions were mandated?

(2) Require that owners and parent companies register, list, and take responsibility for the registration and listing of their establishments. What is the highest level in a company that should be responsible for registration and listing, and how should this level be defined/described?

(3) Require that additional data elements be submitted to FDA, e.g., premarket submission numbers for those devices that have gone through the premarket notification (510(k)), premarket approval, or product development protocol process.

(4) Because of the ease of submission through the WEB, require that firms register and list within 5 days (current requirement is 30 days) of entering into an operation that requires registration and listing.

A summary report of the meeting will be available on CDRH's website approximately 15 working days after the meeting. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

Dated: April 19, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10140 Filed 4–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0693]

''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test.'' The guidance document is intended to provide guidance to applicants on the content and format of the chemistry, manufacturing and controls (CMC) and establishment description sections of the ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' (revised Form FDA 356h) for an allergenic extract or allergen patch test. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 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. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax 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 document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test.'' The guidance document is intended to provide guidance to applicants in completing the CMC section and the establishment description information of revised Form FDA 356h. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test'' published in the **Federal Register** of August 27, 1998 (63 FR 45826).

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a revised Form FDA 356h that will be used as a single harmonized application form for all drug and licensed biological products. Manufacturers may voluntarily begin using this form for an allergenic extract or allergen patch test. FDA will announce in the future when manufacturers are required to use this form for all products. Use of the new harmonized Form FDA 356h will allow a biologic product manufacturer to submit one biologics license application instead of two separate applications (product license application and establishment license application).

This guidance document represents the agency's current thinking with regard to the content and format of the CMC and establishment description sections of a license application for an allergenic extract or allergen patch test. 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document 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 using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: April 16, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10228 Filed 4–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–278]

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 of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection;

Title of Information Collection: National Hospital Malpractice Insurance Survey;

Form No.: HCFA–R–278 (OMB# 0938–NEW);

Use: The Data collected from this survey will be used to collect two years of malpractice insurance costs data from a nationally representative sample of 800 hospitals. Along with the survey of hospitals, we will collect rate schedules from the commercial insurers and the offices of state insurance commissioners. As compared to the survey of hospitals which is a statistical sampling survey, the survey of the offices of state insurance commissioners and commercial insurance companies will not be a statistical sampling survey. We will match collected data in the rate schedules to the data from sampled hospitals in order to convert malpractice insurance costs of different level of coverage into costs of a constant level of coverage. The primary statistics will be used to rebase the input price index through weight adjustment and the annual percent change to update the operating prospective payment rates. Therefore, the NHMIS must allow estimates of the primary statistics for each hospital be adjusted by their rating basis, coverage elements, and types of coverage. The survey results will be used to estimate the weight of malpractice insurance costs in relation to goods and services hospitals purchase in order to furnish inpatient care and to calculate the malpractice insurance cost to change over time at the national level. The analytic results will be used to adjust Medicare operating reimbursement rates to Medicare participating hospitals and to prepare statistical summaries.;

Frequency: Annually;

Affected Public: Not-for-profit institutions, business or other for-profit, and State, Local, or Tribal Govt.;

Number of Respondents: 600;

Total Annual Responses: 600;

Total Annual Hours: 300.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your