

26. How should individuals/parents have access to registry information on themselves/their children?

27. Should data maintained in a state and community-based immunization registry be considered public information?

28. Would national privacy and confidentiality standards help ensure that data maintained in an immunization registry is protected?

Ensuring Provider Participation Questions To Be Considered

1. What type of resources (e.g., hardware, staff, etc.) are needed for you (provider/organization) to participate in a computerized registry?

2. What are the cost-related barriers that keep you (provider/organization) from participating in an immunization registry?

3. What cost should providers be responsible for, pertaining to participation in immunization registry systems?

4. What are the cost savings you would anticipate as a result of participating in a computerized registry (e.g., increased return visit form reminders, less personnel paperwork for preschool exams, etc.)?

5. How much time would you be willing to invest per patient visit (e.g., additional 1, 5, 7, 10 minutes) in the overall success of an immunization registry?

6. What type of user support would be needed in order for you (provider/organization) to participate in an immunization registry?

7. How would you (provider/organization) encourage providers and consumers in your community to participate in an immunization registry?

8. What community support would be necessary for you to participate in the immunization registry?

9. What benefits/value (e.g., immunization reminders, quick access to immunization histories, etc.) would a registry provide that would encourage your (provider/organization) participation?

10. What incentives should be offered to providers/organizations to participate in an immunization registry?

11. What barriers have you (provider/organization) encountered that have prevented you from participating in an immunization registry?

12. Is provider liability (e.g., disclosure of sensitive patient information) a barrier to participating in an immunization registry? Why?

13. How would an immunization registry impact your practice/organization?

14. Do you currently share immunization data with other providers electronically? For what purpose (e.g., billing, share group data, etc.)?

15. How (e.g., electronic record, paper record) is medical information maintained in your practice/organization?

16. Who should retain ownership of immunization records as they are distributed throughout an immunization registry?

17. How would you (provider/organization) use the data maintained in an immunization registry?

18. What type of quality control process would you (provider/organization) perform

to ensure the accuracy and completeness of the immunization data entered into an immunization registry?

19. What type of security policies and procedures need to be in place for you to be confident that data are secure?

20. What functions should a registry perform in your office in order for you (provider/organization) to participate?

21. Do you have any advice or recommendations for NVAC/CDC/HHS related to the implementation of the network of state and community-based registries and do you have any concerns?

22. Do you feel that there is a need for the Federal Government to provide leadership in developing state and community-based immunization registries? What should the role of the Federal Government be in this effort?

23. Have you received training on the use and maintenance of computerized medical information? Do you feel this training is needed to fully support the development and maintenance of immunization registries?

Contact Person for More Information: Robb Linkins, M.P.H., Ph.D., Chief, Systems Development Branch, Data Management Division, NIP, CDC, 1600 Clifton Road, NE, M/S E-62, Atlanta, GA 30333, telephone (404) 639-8728, e-mail rxl3@cdc.gov.

Dated: April 22, 1998.

Joseph E. Salter,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-11185 Filed 4-27-98; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D-0349]

Draft Guidance for Industry on SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum; 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 "SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum." This draft guidance is intended to provide insight and recommendations to pharmaceutical sponsors of new drug applications (NDA's) and abbreviated new drug applications (ANDA's) who wish to change equipment during the postapproval period.

DATES: Written comments may be submitted on the draft guidance

document by June 29, 1998. 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." Written requests for single copies of the draft guidance for industry should be submitted 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John L. Smith, Center for Drug Evaluation and Research (HFD-590), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301-827-2175.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum." This draft guidance is intended to provide recommendations to pharmaceutical manufacturers using CDER'S Guidance for Industry on "Immediate Release Solid Oral Dosage Forms, Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation" (SUPAC-IR), which published in November 1995, and CDER's Guidance for Industry "SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation," which published in September 1997.

This draft guidance is a revision of the guidance entitled "SUPAC-IR: Immediate Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum" that published in October 1997, and the draft guidance is intended to supersede the previously published guidance. The draft guidance includes information on equipment used to manufacture modified release solid oral dosage form products as well as immediate release solid oral dosage form products and may be used to determine what documentation should be submitted to FDA regarding equipment changes made in accordance with the recommendations in sections V and VI.A of the SUPAC-IR guidance

and in sections VI and VII of the SUPAC-MR guidance.

This draft guidance represents the agency's current thinking on scale-up and postapproval equipment changes for immediate release and modified release solid oral dosage forms regulated by CDER. 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: April 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-11197 Filed 4-27-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0238]

Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices." This guidance is not final or in effect at this time. The purpose of this document is to suggest to the device manufacturer or investigation sponsor important information which should be presented in investigational device exemption (IDE) and premarket approval (PMA) applications in order to provide reasonable assurance of the safety and

effectiveness of these devices for their intended uses.

DATES: Written comments concerning this guidance must be submitted by July 27, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices" to the Division of Small Manufacturers Assistance, Center for Devices and Radiological (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Written comments concerning this guidance document must be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John S. Goode, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036.

SUPPLEMENTARY INFORMATION:

I. Background

The preparation of a guidance document for Bone Growth Stimulator applications was first initiated by the Division of Surgical and Rehabilitation Devices (DSRD) of the Office of Device Evaluation (ODE) in conjunction with the Division of Physical Sciences (DPS) and Life Sciences (DLS) of the Office of Science and Technology in 1985. The purpose of the document was to suggest to the device manufacturer or investigation sponsor important information which should be presented in IDE and PMA applications in order to provide reasonable assurance of the safety and effectiveness of these devices for their intended uses. The document went through extensive review by representatives of DSRD, DPS, DLS, the Orthopedic and Rehabilitation Devices (ORD) Advisory Panel, and industry representatives. Comments and recommendations generated by these reviews resulted in a revised draft document, which was presented for discussion during an open public session of the ORD Advisory Panel meeting held on October 31, 1986.

Subsequent to the panel meeting, the Health Industry Manufacturers Association organized a task force which again reviewed the document and suggested changes to the Center for Devices and Radiological Health (CDRH) on February 15, 1988. As a result, a final guidance document was issued on August 12, 1988. This revised draft of the guidance document was initiated in response to discussions and correspondences with sponsors of bone growth stimulator devices and other interested parties, and it provides additional guidance detailing the ODE's present perspective on issues relating to these devices. The revised draft guidance will be considered by the ORD Advisory Panel in a meeting to be held on April 28, 1998, at 9200 Corporate Blvd., Rockville, MD.

II. Significance of Guidance

This guidance document represents the agency's current thinking on IDE and PMA applications for Bone Growth Stimulators. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive copies of the draft guidance document entitled "Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (487) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a