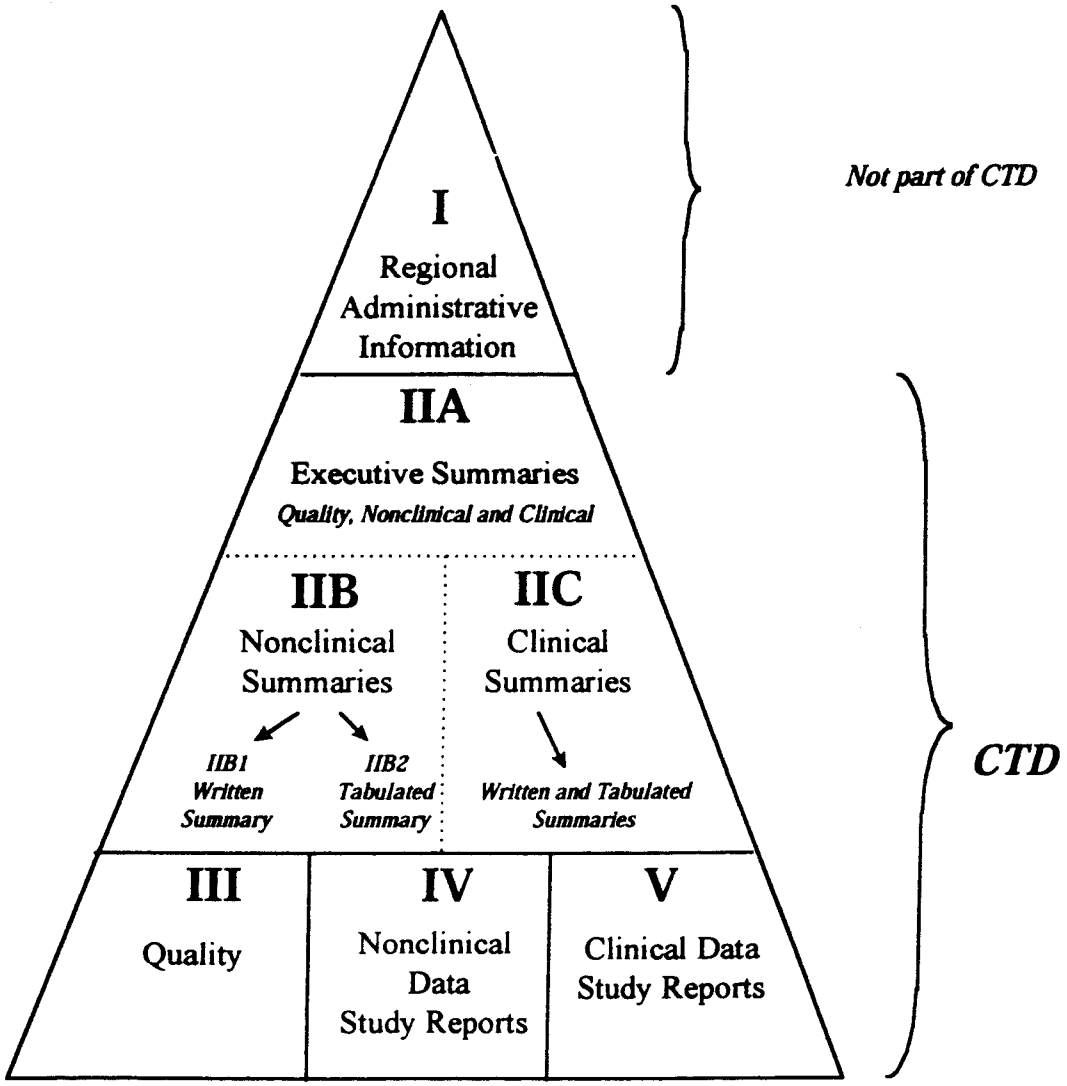
Diagram 1: Diagrammatic Representation of the ICH Common Technical Document



Dated: February 8, 2000.

Margaret Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–3343 Filed 2–9–00; 11:32 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0053]

Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; and Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidance documents entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme;'' and ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.'' These draft guidance documents are neither final, nor are they in effect at this time. The review prioritization scheme guidance document sets forth factors FDA (we) would consider in categorizing a reprocessed single-use device (SUD) as high, moderate, or low risk. The enforcement priorities guidance document sets forth our priorities for various requirements based on the risk categorization of a device.

DATES: Submit written comments concerning either guidance by April 11, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies (on a 3.5 diskette) of the guidance documents entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme'' and ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, 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. Submit written comments concerning these guidances to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Regarding ''Reprocessing and Reuse Of Single-Use Devices: Review Prioritization Scheme,'' Barbara C. Zimmerman, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

Regarding ''Enforcement Priorities For Single-Use Devices Reprocessed by Third Parties and Hospitals,'' Larry D. Spears, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4646.

SUPPLEMENTARY INFORMATION:

I. Background

The practice of reprocessing devices that are intended for single-use (SUD's) began in hospitals in the late 1970's. Since that time, the practice has become widespread. We have not regulated original equipment manufacturers (OEM's), third parties, and hospitals that engage in reprocessing SUD's in the same manner. In particular, to date, we have enforced existing premarket submission requirements only against OEM's.

In response to concerns raised by original equipment manufacturers and consumers about safety issues associated with reprocessing SUD's, in the **Federal Register** of November 3, 1999 (64 FR 59782), we announced a proposed strategy on reuse of SUD's. The essence of this proposed strategy was to regulate OEM's, third parties, and hospitals that reprocess SUD's in the same manner.

On December 14, 1999, we held a public meeting to provide the opportunity to interested parties to comment on its proposed strategy. We received comments on the proposed strategy from OEM's, third party reprocessors, health-care professionals, and other interested parties, both during and subsequent to this meeting.

One of the principle components of our proposed strategy was the establishment of agency enforcement priorities concerning regulatory requirements for third party and hospital reprocessors of SUD's. We proposed to prioritize its enforcement activities based on the degree of risk posed by the reprocessing. To accomplish this process, we proposed the following steps:

(1) Develop a list of commonly reused SUD's;

(2) Develop a list of factors to determine the degree of risks associated with reprocessing devices;

(3) Use that list of factors to divide the list of commonly reprocessed SUD's into three categories of risk—high, moderate, and low; and

(4) Develop priorities for enforcement of regulatory requirements for hospitals and third party reprocessors, based on the category of risk (high, moderate, and low).

We received many comments expressing concern that we were proposing to develop a new regulatory system for reprocessed SUD's that was outside of the current classification system under section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) for class I, II, and III devices. We clarified at the meeting that the categorization of devices by risk would be used solely in setting enforcement priorities; it would not entail a process outside of the current classification system.

Under the proposed strategy, devices would still be classified as class I, II, and III and still have premarket notification (510(k)) or premarket approval (PMA) requirements based on that classification. The proposed prioritization scheme would only apply to our enforcement priorities, it would not relate to established premarket submission requirements. For example, if we categorized a certain type of device as high risk under the prioritization scheme, it would mean that we would set the enforcement of regulatory requirements for that device as the highest priority. It would not affect the classification of the device or the type of marketing submission that would be required for that device. If the generic type of that device were class III, we would generally require an approved PMA application before marketing. If the generic type of device were class II, we would require clearance of a 510(k) before marketing. A high risk categorization, therefore, would affect the timing of our enforcement of these requirements rather than the requirements themselves.

We are issuing two companion draft guidance documents that would implement our proposed enforcement strategy:

(1) One draft guidance is entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme.'' This draft guidance sets forth factors we would consider in categorizing a reprocessed device as high, moderate, or low risk, which we would use in setting our enforcement priorities. An appendix to the guidance lists commonly reprocessed SUD's, and lists what category of risk we believe a particular device falls within if reprocessed.

On December 9, 1999, we published an earlier version of the guidance document on our Internet site. The **Federal Register** document announcing this earlier draft guidance version was published on February 2, 2000 (65 FR 4985).

The revised draft guidance document incorporates comments we received at the December 14, 1999, public meeting and written submissions, and includes the risk category that we believe a particular device falls within if reprocessed. This revised guidance replaces the earlier version, however, it is a draft guidance that is not in effect at this time.

(2) The other draft guidance document is entitled ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.'' This draft guidance document sets forth our priorities for enforcing various regulatory requirements, based on the categorization of a device, as described in the risk categorization guidance.

II. Significance of Guidance

These guidance documents represent the agency's current thinking on the factors we would consider in categorizing a reprocessed device as high, moderate, or low risk. They also identify how commonly reprocessed devices might be categorized and how this categorization affects the agency's regulatory priorities.

These guidance documents do not create or confer any rights for or on any person and do not operate to bind us or the public.

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

III. Electronic Access

In order to receive these draft guidance documents 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 (1156– Reprocessing

and Reuse of Single-Use Devices: Review Prioritization Scheme) or (1029–Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of these guidance documents may do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance documents entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme'' and ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme'' will be available at http://www.fda.gov/cdrh/ODE. ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' will be available at http://www.fda.gov/cdrh/OC.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding these draft guidance documents by April 11, 2000. 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 documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 8, 2000,

Margaret Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–3345 Filed 2–9–00; 12:28 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of March 2000.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 1, 2000; 9 a.m.–5 p.m.

Place: Parklawn Building,Conference Rooms G&H,5600 Fishers Lane,Rockville, Maryland 20857.

The meeting is open to the public.

The full Commission will meet on Wednesday, March 1, 2000, from 9 a.m. to 5 p.m. Agenda items will include, but not be limited to: A presentation on the Government Accounting Office Report, a discussion on exemptions provided under state laws for philosophical and religious reasons in vaccinations; updates from the Department of Justice and the National Vaccine Program Office; and routine program reports.

Public comment will be permitted before lunch and at the end of the Commission meeting on March 1, 2000. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Shelia Tibbs, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–1896. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but desire to make an oral statement, may sign-up in Conference Rooms G and H on March 1, 2000. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Ms. Tibbs, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1896.

Agenda items are subject to change as priorities dictate.

Dated: February 4, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–3170 Filed 2–10–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: February 16, 2000.

Time: 3 pm to 4 pm.

Agenda: To review and evaluate grant applications.

Place: Georgetown Holiday Inn, 2101 Wisconsin Avenue, NW, Wasington, DC 20007.

Contact Person: Zakir Bengali, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, MSC 7842, Bethesda, MD 20892, (301) 435–1742.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: February 18, 2000.

Time: 11 am to 12:30 pm.

Agenda: To review and evaluate grant applications.

Place: Georgetown Holiday Inn, 2101 Wisconsin Avenue, NW, Washington, DC 20007.

Contact Person: Zakir Bengali, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, MSC 7842, Bethesda, MD 20892, (301) 435–1742.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.