TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Total Hours | | | | | 48,644 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[2]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 99.501(a)(1) | 172 | 1.7 | 297 | 10 | 2,970 |
| 99.501(a)(2) | 172 | 1.7 | 297 | 1 | 297 |
| 99.501(c) | 172 | 1.7 | 297 | 1 | 297 |
| Total Hours | | | | | 3,564 |

[2] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden associated with the information collection requirements for this rule is 52,208 hours.

Dated: July 15, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99–18767 Filed 7–22–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing changes to its Orphan Products Development (OPD) grant program for fiscal year (FY) 2000. The previous announcement of this program, which was published in the Federal Register of August 5, 1998 (63 FR 41855), is superseded by this announcement. In the future, a new announcement will be published annually.

**DATES:** The application receipt dates are November 15, 1999, and April 3, 2000.

**ADDRESSES:** Application forms are available from, and completed applications should be submitted to: Maura C. Stephanos, Grants Management Specialist, Division of Contracts and Procurement Management (HFA–522), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183. (Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20852.)

**FOR FURTHER INFORMATION CONTACT:**

Regarding the administrative and financial management aspects of this notice: Maura C. Stephanos (address above).

Regarding the programmatic aspects of this notice: Ronda A. Balham, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 8–73, Rockville, MD 20857, 301–827–3666.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the anticipated availability of funds for FY 2000 for awarding grants to support clinical trials on the safety and effectiveness of products for a rare disease or condition (i.e., one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Contingent on availability of FY 2000 funds, it is anticipated that $11.5 million will be available, of which $8.5 million will be for noncompeting continuation awards. This will leave $3 million for funding approximately 10 new applications. Any phase clinical trial is eligible for up to $100,000 in direct costs per annum plus applicable indirect costs for up to 3 years. Phase 2 and phase 3 clinical trials are eligible for up to $200,000 in direct costs per annum plus applicable indirect costs for up to 3 years.

FDA will support the clinical studies covered by this notice under section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free work place and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

PHS urges applicants to submit work plans that address specific objectives of ''Healthy People 2000.'' Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, stock no. 017–001–00474–0) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, 202–512–1800.

PHS policy is that applicants for PHS clinical research grants are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

#### I. Program Research Goals

OPD was established to identify and facilitate the availability of orphan products. In the OPD grant program, orphan products are defined as drugs, biologics, medical devices, and foods for medical purposes that are indicated for a rare disease or condition (i.e., one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostic tests and vaccines will qualify only if the U.S. population of intended use is lower than 200,000 per annum.

One way to make orphan products available is to support clinical research to determine whether the products are safe and effective. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued thereunder. The grants are funded under the legislative authority of section 301 of the PHS Act (42 U.S.C. 241).

The goal of FDA's OPD grant program is the clinical development of products for use in rare diseases or conditions where no current therapy exists or where current therapy would be improved. FDA provides grants to conduct clinical studies intended to provide data acceptable to the agency which will either result in or substantially contribute to approval of these products. Applicants should keep this goal in mind and must include an explanation in the ''Background and Significance'' section of the application of how their proposed study will either facilitate product approval or provide essential data needed for product development. Information regarding meetings and/or discussions with FDA reviewing division staff about the product to be studied should also be provided as an appendix to the application. This information is extremely important for the review process.

Except for medical foods that do not require premarket approval, FDA will only consider awarding grants to support clinical studies for determining whether the products are safe and effective for premarket approval under the act (21 U.S.C. 301 *et seq.*) or under section 351 of the PHS Act (42 U.S.C. 262). All studies of new drug and biological products must be conducted under the FDA's investigational new drug (IND) procedures and studies of medical devices must be conducted under the investigational device exemption (IDE) procedures. Studies of approved products to evaluate new orphan indications are also acceptable; however, these are also required to be conducted under an IND or IDE to support a change in labeling. (See section V.B of this document (''Program Review Criteria'') for critical requirements concerning IND/IDE status of products to be studied under these grants.)

Studies submitted for the larger grants ($200,000) must be continuing in phase 2 or phase 3 of investigation. Phase 2 trials include controlled clinical studies conducted to evaluate the effectiveness of the product for a particular indication in patients with the disease or condition and to determine the common or short-term side effects and risks associated with it. Phase 3 trials gather additional information about effectiveness and safety that is necessary to evaluate the overall risk-benefit relationship of the product and to provide an adequate basis for physician labeling. Studies submitted for the smaller grants ($100,000) may be phase 1, 2, or 3 trials. If a study is submitted as a phase 1/2 trial, the maximum budget support for all years requested may not exceed $100,000 per year. Budgets for all years of requested support may not exceed the $200,000 or $100,000 limitation, whichever is applicable.

Applications must propose a clinical trial of one therapy for one indication. The applicant must provide supporting evidence that a sufficient quantity of the product to be investigated is available to the applicant in the form needed for the clinical trial. The applicant must also provide supporting evidence that the patient population has been surveyed and that there is reasonable assurance that the necessary number of eligible patients is available for the study.

Funds may be requested in the budget for travel to FDA to meet with reviewing division staff about product development progress.

## II. Human Subject Protection and Informed Consent

### *A. Protection of Human Research Subjects*

Some activities carried out by a recipient under this announcement may be governed by the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects (45 CFR part 46). These regulations require recipients to establish procedures for the protection of subjects involved in any research activities. Prior to funding and upon request of the Office for Protection from Research Risks (OPRR), prospective recipients must have on file with OPRR an assurance to comply with 45 CFR part 46. This assurance to comply is called an Assurance document. It includes the designated Institutional Review Board (IRB) for review and approval of procedures for carrying out any research activities occurring in conjunction with this award. If an applicable Assurance document for the applicant is not already on file with OPRR, a formal request for the required Assurance will be issued by OPRR at an appropriate point in the review process, prior to award, and examples of required materials will be supplied at that time. No applicant or performance site, without an approved and applicable Assurance on file with OPRR, may spend funds on human subject activities or accrue subjects. No performance site, even with an OPRR-approved and applicable Assurance, may proceed without approval by OPRR of an applicable Assurance for the recipients. Applicants may wish to contact OPRR by fax (301–402–0527) to obtain preliminary guidance on human subjects issues. When contacting OPRR, applicants should provide their institutional affiliation, geographic location, and all available Request For Applications (RFA) citation information.

Applicants are advised that the section on human subjects in the application kit entitled ''Section C. Specific Instructions—Forms, Item 4, Human Subjects,'' on pages 7 and 8 of the application kit, should be carefully reviewed for the certification of IRB approval requirements. Documentation of IRB approval for every participating center is required to be on file with the Grants Management Officer, FDA. The goal should be to include enough information on the protection of human subjects in a sufficiently clear fashion so reviewers will have adequate material to make a complete review. Those approved applicants who do not have a current Multiple Project Assurance with OPRR will be required to obtain a Single Project Assurance from OPRR prior to award.

### *B. Informed Consent*

Consent and/or assent forms, and any additional information to be given to a subject, should accompany the grant application. Information that is given to the subject or the subject's representative must be in language that the subject or his or her representative can understand. No informed consent, whether oral or written, may include any language through which the subject or the subject's representative is made to waive any of the subject's legal rights, or by which the subject or representative releases or appears to release the investigator, the sponsor, or the institution or its agent from liability.

If a study involves both adults and children, separate consent forms should be provided for the adults and the parents or guardians of the children.

### *C. Elements of Informed Consent*

The elements of informed consent are stated in the regulations at 45 CFR 46.116 and 21 CFR 50.25 as follows:

1. Basic elements of informed consent.

In seeking informed consent, the following information shall be provided to each subject.

(a) A statement that the study involves research, an explanation of the

purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(b) A description of any reasonably foreseeable risks or discomforts to the subject.

(c) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(e) A statement that describes the extent, if any, to which confidentiality of records identifying the subject will be maintained, and that notes the possibility that FDA may inspect the records.

(f) For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.

(g) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research-related injury to the subject.

(h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional elements of informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each subject.

(a) A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(c) Any costs to the subject that may result from participation in the research.

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(f) The approximate number of subjects involved in the study. The informed consent requirements are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

Nothing in the notice is intended to limit the authority of a physician to provide emergency medical care to the extent that a physician is permitted to do so under applicable Federal, State, or local law.

## III. Reporting Requirements

An annual Financial Status Report (SF–269) is required. The original and two copies of this report must be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the grant. Failure to file the Financial Status Report (SF–269) in a timely fashion will be grounds for suspension or termination of the grant.

For continuing grants, an annual program progress report is also required. The noncompeting continuation application (PHS 2590) will be considered the annual program progress report.

Additionally, all new and continuing grants must comply with all regulatory requirements necessary to maintain active status of their IND/IDE. This includes, but is not limited to, submission of an annual report to the appropriate regulatory review division within the FDA. Failure to meet regulatory requirements will be grounds for suspension or termination of the grant.

Program monitoring of grantees will be conducted on an ongoing basis and written reports will be prepared by the project officer. The monitoring may be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator. Periodic site visits with appropriate officials of the grantee organization may also be conducted. The results of these reports will be recorded in the official grant file and may be available to the grantee upon request consistent with FDA disclosure regulations. Additionally, the grantee organization will be required to comply with all Special Terms and Conditions which state that future funding of the study will be contingent on recommendations from the OPD Project Officer verifying that: (1) There has been adequate progress toward enrollment, based on specific circumstances of the study; (2) there is an adequate supply of the product/device; and (3) there is continued compliance with all FDA regulatory requirements for the trial (e.g., annual report to IND/IDE file, communication of all protocol changes to the appropriate FDA Center, etc.).

A final program progress report, a Final Financial Status Report (SF–269), and an Invention Statement must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

## IV. Mechanism of Support

### *A. Award Instrument*

Support will be in the form of a grant. All awards will be subject to all policies and requirements that govern the research grant programs of PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program. All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the act (21 U.S.C. 355, 360b, and 360e), section 351 of the PHS Act (42 U.S.C. 262), and regulations issued under any of these sections.

### *B. Eligibility*

These grants are available to any public or private nonprofit entity (including State and local units of government) and any for-profit entity. For-profit entities must commit to excluding fees or profit in their request for support to receive grant awards. Organizations described in section 501(c)4 of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive grant awards

### *C. Length of Support*

The length of the study will depend upon the nature of the study. For those studies with an expected duration of more than 1 year, a second or third year of noncompetitive continuation of support will depend on: (1) Performance during the preceding year, (2) the availability of Federal funds, and (3) compliance with regulatory requirements of the IND/IDE.

### *D. Funding Plan*

The number of studies funded will depend on the quality of the applications received and the availability of Federal funds to support the projects. Before an award will be made, OPD will verify the active status of the IND/IDE for the proposed study. If the IND/IDE for the proposed study is not active or if an annual report has not been submitted to the IND file in the last 12 months, no award will be made. Further, documentation of IRB approvals for all performance sites must

be on file with the Grants Management Officer, FDA (address above), before an award can be made.

## V. Review Procedure and Criteria

*A. Review Method*

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness to this RFA. If applications are found to be nonresponsive, they will be returned to the applicant without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence with the recommendations made by the first-level reviewers, and funding decisions will be made by the Commissioner of Food and Drugs.

*B. Program Review Criteria*

Applications will be evaluated by program and grants management staff for responsiveness. Applications considered nonresponsive will be returned to the applicant, without being reviewed. Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their application. All questions of a technical or scientific nature must be directed to the OPD program staff and all questions of an administrative or financial nature must be directed to the grants management staff. (See **FOR FURTHER INFORMATION CONTACT** section of this document.) Responsiveness will be based on the following criteria:

1. The application must propose a clinical trial intended to provide safety and/or efficacy data of one therapy for one orphan indication. Additionally, there must be an explanation in the ''Background and Significance'' section of how the proposed study will either facilitate product approval or provide essential data needed for product development.

2. The prevalence, not incidence, of population to be served by the product must be fewer than 200,000 individuals in the United States. The applicant should include, in the ''Background and Significance'' section, a detailed explanation supplemented by authoritative references in support of the prevalence figure. If the product has been designated by FDA as an orphan product for the proposed indication, a statement of that fact will suffice. Diagnostic tests and vaccines will qualify only if the population of intended use is fewer than 200,000 individuals in the United States per annum.

3. The number assigned to the IND/IDE for the proposed study should appear on the face page of the application with the title of the project. Only medical foods that do not require premarket approval are exempt from this requirement. The IND/IDE must be in active status and in compliance with all regulatory requirements of FDA at the time of submission of the application. In order to meet this requirement, the original IND/IDE application, pertinent amendments, and the protocol for the proposed study must have been received by the appropriate FDA reviewing division a minimum of 30 days prior to the due date of the grant application. Studies of already approved products, evaluating new orphan indications, must also have an active IND. Exempt IND's must have their status changed to active to be eligible for this program. If the sponsor of the IND/IDE is other than the principal investigator listed on the application, a letter from the sponsor verifying access to the IND/IDE is required, and both the application's principal investigator and the study protocol must have been submitted to the IND/IDE.

4. The requested budget should be within the limits (either $100,000 in direct costs for each year for up to 3 years for any phase study, or $200,000 in direct costs for each year for up to 3 years for phase 2 or 3 studies) as stated in this request for applications. Multi-phase studies that include phase I are only eligible for $100,000 per annum for the entire 3-year period. Any application received that requests support in excess of the maximum amount allowable for that particular study will be considered nonresponsive and returned to the applicant unreviewed.

5. Consent and/or assent forms, and any additional information to be given to a subject, should be included in the grant application.

6. All applicants should follow guidelines specified in the PHS 398 Grant Application kit.

7. Evidence that a sufficient quantity of the product is available to the applicant in the form needed for the investigation must be included in the application. A current letter from the supplier as an appendix will be acceptable.

*C. Scientific/Technical Review Criteria*

The ad hoc expert panel will provide the first level of review. The application will be judged on the following scientific and technical merit criteria:

1. The soundness of the rationale for the proposed study;

2. The quality and appropriateness of the study design to include the rationale for the statistical procedures;

3. The statistical justification for the number of patients chosen for the trial, based on the proposed outcome measures and the appropriateness of the statistical procedures to be used in analysis of the results;

4. The adequacy of the evidence that the proposed number of eligible subjects can be recruited in the requested timeframe;

5. The qualifications of the investigator and support staff, and the resources available to them;

6. The adequacy of the justification for the request for financial support;

7. The adequacy of plans for complying with regulations for protection of human subjects; and

8. The ability of the applicant to complete the proposed study within its budget and within time limitations stated in this RFA.

The priority score will be based on the scientific/technical review criteria in section V.C of this document. In addition, the reviewers may advise the program staff concerning the appropriateness of the proposal to the goals of the OPD Grant Program described in section I (Program Research Goals) of this document.

*D. Award Criteria*

Resources for this program are limited. Therefore, should two or more applications be received and approved by FDA which propose duplicative or very similar studies, FDA will support only the study with the best score.

## VI. Submission Requirements

The original and five copies of the completed Grant Application Form PHS 398 (Rev. 5/95) or the original and two copies of the PHS 5161 (Rev. 7/92) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura C. Stephanos (address above). State and local governments may choose to use the PHS 398 application form in lieu of the PHS 5161. The application receipt dates are November 15, 1999 and April 3, 2000. No supplemental or addendum material will be accepted after the receipt date. Evidence of final IRB approval will be accepted for the file after the receipt date.

The outside of the mailing package and item 2 of the application face page should be labeled, ''Response to RFA FDA OPD–2000.''

If an application for the same study was submitted in response to a previous RFA, but has not yet been acted upon, a submission in response to this RFA will be considered a request to withdraw the previous application. Resubmissions are treated as new applications; therefore, the applicant may wish to address the issues presented in the summary statements from the previous review.

**VII. Method of Application**

*A. Submission Instructions*

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt dates.

Applications will be considered received on time if sent or mailed on or before the receipt dates as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH). Any application that is sent to the NIH, that is then forwarded to FDA and received after the applicable due date, will be deemed unresponsive and returned to the applicant. Instructions for completing the application forms can be found on the NIH home page on the Internet (address ''http://www.nih.gov/grants/funding/phs398/phs398.html''; the forms can be found at ''http://www.nih.gov/grants/funding/phs398/forms—toc.html''). However, as noted previously, applications are not to be mailed to the NIH. Applicants are advised that the FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by the NIH on its applications). Applications must be submitted via mail delivery as stated previously. FDA is unable to receive applications via the Internet.

*B. Format for Application*

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/95). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to the CSR, NIH. Applications from State and Local Governments may be submitted on Form PHS 5161 (Rev. 7/92) or Form PHS 398 (Rev. 5/95).

The face page of the application should reflect the request for applications number RFA–FDA–OPD–000. The title of the proposed study should include the name of the product and the disease/disorder to be studied along with the IND/IDE number. The format for all subsequent pages of the application should be single-spaced and single-side.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

*C. Legend*

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the DHHS or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: July 15, 1999

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99–18771 Filed 7–22–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee*: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on August 2, 1999, 8 a.m. to 5 p.m.

*Location*: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

*Contact Person*: Martha T. O'Lone, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12520. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committee will discuss possible revisions to the 1995 draft guidance entitled ''Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices With Sharps Injury Prevention Features.'' The committee will also discuss the development of guidance for needle-free devices such as jet injectors intended for the delivery of drugs and biologics and the need for and content of educational programs to encourage the safe and effective use of these devices. Single copies of the 1995 draft guidance are available to the public by calling 1–800–899–0381 or 301–827–0111, and requesting Facts-on-Demand document number 934, or on the Internet using the World Wide Web (WWW) ''http://www.fda.gov/cdrh/ode/doc934.pdf''.

*Procedure*: On August 2, 1999, from 8:30 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 23, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. and between approximately 3:45 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those individuals desiring to make formal oral presentations should notify the contact person by July 23, 1999, and submit a brief statement of the general nature of the evidence or