cooperation, early medical screening for children, work requirements, drug and alcohol abuse, school attendance, and parenting skills training; would limit the caretaker exemption from employment services, disregard the earned income and resources from earnings of a child, set resource limits which promote independence from AFDC, eliminate work history and 100-hour rules for otherwise eligible two-parent families. In Bexar County would time-limit AFDC benefits to 12, 24, and 36 months depending on education and job experience, with extensions of the time-limit based on severe personal hardship, or in cases where the State could not provide supportive services, or where the local economy was in such state that the recipient could not reasonably be expected to find employment, if State funds are available to continue assistance. Transitional Medicaid and child care services would be provided to individuals who exhaust their time-limited cash benefits. In two metropolitan statistical areas establish Individual Development Accounts to promote the transition to independence from AFDC, through allowable account deductions for education, business start-up costs and the like. In Fort Bend County would allow at recipient option, one-time AFDC cash emergency assistance payments of $1,000 in lieu of ongoing regular AFDC payments with prohibition from applying for regular AFDC for a period of 12 months from date of receipt. In Dallas-Fort Worth would require electronic imaging (fingerprinting combined with photographic identification).

Date Received: 10/6/95.

Title: AFDC/Medicaid.

Current Status: Pending.

Contact Person: Kent Gummerman, (512) 438–3743.

Project Title: Utah—Single-Parent Employment Demonstration (Amendments)

Description: Would amend the current Single Parent Employment Demonstration (SPED), requiring preschool children to be immunized and other children to attend school; considering as a single filing unit each family with a child in common, including all children in the household related to either parent; permitting parents removed from the grant due to non-cooperation or fraud to remain eligible for JOBS services, including support services; and allowing a ''best estimate'' of earnings in lieu of actual earnings so long as estimate is within $100 of actual earnings. These amendments would initially be limited to the Kearns office and later expanded to other SPED sites.

Date Received: 2/7/96.

Type: AFDC.

Current Status: New.

Contact Person: Bill Biggs, (801) 538–4337.

III. Listing of Approved Proposals Since February 1, 1995

Project Title: California—Assistance Payments Demonstration Project (Amendment)

Contact Person: Bruce Wagstaff, (916) 657–2367.

Project Title: Louisiana—Individual Responsibility Project.

Contact Person: Sammy Guillory, (504) 342–4089.

Project Title: Mississippi—A New Direction Demonstration Program—Amendment.

Contact Person: Larry Temple, (601) 359–4476.

Project Title: North Carolina—Work First Program.

Contact Person: Kevin Fitzgerald, (919) 733–3055.

IV. Requests for Copies of a Proposal

Requests for copies of an AFDC or combined AFDC/Medicaid proposal should be directed to the Administration for Children and Families (ACF) at the address listed above. Questions concerning the content of a proposal should be directed to the State contact listed for the proposal.

(Catalog of Federal Domestic Assistance Program, No. 93562; Assistance Payments—Research)

Dated: March 1, 1996.

Howard Rolston,

Director, Office of Planning, Research and Evaluation.

[FR Doc. 96–5338 Filed 3–6–96; 8:45 am]

BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 95P–0110]

Guidance Documents; The Food and Drug Administration's Development and Use; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comment on issues relating to the agency's development and use of guidance documents. These issues were raised in a citizen petition submitted by the Indiana Medical Devices Manufacturers Council, Inc. (IMDMC). (See Docket No. 95P–0110). The petition requested that FDA control the initiation, development, and issuance of guidance documents by written procedures that assure the appropriate level of meaningful public participation. In its response to the petition, FDA agreed that public participation generally benefits the guidance document development process. FDA also stated the importance of communicating more clearly to its employees and to the public the nonbinding nature of guidance documents. Therefore, FDA agreed to take steps to improve its guidance document procedures. FDA is seeking an approach that addresses concerns regarding adequate public participation but does not make it impractical for the agency to continue making guidance available in a timely fashion. Some suggestions for improving FDA's guidance document procedures are set forth in this document. FDA is soliciting comment on these suggestions and is soliciting additional recommendations for improving its guidance document procedures. A public meeting on these issues will be held at least 30 days before the end of the comment period. The agency will announce the details of that meeting in a future issue of the Federal Register.

DATES: Written comments by June 5, 1996.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Margaret M. Dotzel, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. FDA Guidance Documents

For purposes of this document, the term ''guidance documents'' means: (1) Documents prepared for FDA review staff and applicants/sponsors relating to the processing, content, and evaluation/approval of applications and relating to the design, production, manufacturing, and testing of regulated products; and (2) documents prepared for FDA personnel and/or the public that establish policies intended to achieve consistency in the agency's regulatory approach and establish inspection and enforcement procedures. Guidance documents do not include agency reports, general information provided to consumers, documents relating solely to internal FDA procedures, speeches, journal articles and editorials, media interviews, warning letters, or other communications or actions taken by

individuals at FDA or directed to individual persons or firms.

The purpose of FDA's guidance documents is to provide assistance to the regulated industry by clarifying requirements that have been imposed by Congress or promulgated by FDA and by explaining how industry may comply with those statutory and regulatory requirements. Guidance documents provide industry with the kind of specific detail that often is not included in the relevant statutes and regulations. Certain guidance documents provide information about what the agency considers to be the important characteristics of preclinical and clinical test procedures, manufacturing practices, and scientific protocols. Others explain FDA's views on how one may comply with the relevant statutes and regulations and how one may avoid enforcement actions. Guidance documents do not themselves establish legally enforceable rights or responsibilities. Rather, they explain how the agency believes the statutes and regulations apply to industry activities.

Guidance documents also are essential to the efficient administration of FDA's duties. By providing specific review and enforcement approaches, guidance documents help to ensure that FDA's employees implement the agency's mandate in a fair and consistent manner. Thus, when FDA staff are reviewing applications and petitions, they will be looking for the same kinds of supporting evidence from all submitters. Likewise, when field and headquarter enforcement personnel are reviewing companies' activities, they will have guidance in determining which activities comply with the law and which do not. This benefits industry because it helps to ensure a level playing field.

As a general matter, guidance documents reduce uncertainty; their absence would disadvantage the industry. Nevertheless, questions have been raised about guidance document use and the process by which guidance documents are developed and issued. Over the past several months, the agency has been reviewing its development, dissemination, and use of guidance documents to determine what steps it can take to make these processes more transparent and consistent throughout the agency. Representatives from FDA recently met with representatives from the IMDMC to discuss ideas for ''good guidance practices.'' Suggestions for good guidance practices are set forth below. FDA is seeking comment on these suggestions and is seeking additional recommendations for good guidance practices.

A. Nomenclature

Guidance documents currently are issued under a number of different names (e.g., guidelines, guidance, points to consider, blue book memos, compliance policy guides, etc.). Although a distinction can be drawn between certain types of guidance (e.g., compliance policy guides versus points to consider), there often is overlap in the types of information contained in many such documents (e.g., guidance memoranda and points to consider). The agency is seeking comment regarding whether a more standardized nomenclature would improve the public's understanding of the nature of guidance documents and would help to eliminate any confusion regarding which documents are guidance documents and their legal effect.

If a standardized nomenclature is desirable, then the agency would like to hear suggestions regarding a logical classification system. For example, is it appropriate to distinguish guidance based on how it is used (e.g., in the product approval areas versus inspections) or who are the intended users (e.g., FDA reviewers versus FDA inspectors versus the industry)? Also, is there some way to use a subset of the current names for all guidance documents?

If a standardized nomenclature is desired, then the agency also is seeking public comment on the best approach to take regarding the nomenclature for existing guidance documents, which currently are identified under a range of names, including those discussed above. There are major resource implications involved in undertaking a complete renaming of existing guidance documents. Well over a thousand such documents exist. The reprinting costs alone would be prohibitively high. Moreover, because both the public and the agency have been using these documents for some time, there may be confusion if names suddenly are changed. One approach would be to gradually change the names of existing guidance documents. FDA could revise the names of these documents as they are substantively updated or revised. In the meantime, FDA's lists of available guidance would identify existing guidance documents by their current names but under the appropriate category (i.e., the newly adopted nomenclature).

B. Effect of Guidance Documents

A guidance document, though not intended to be a comprehensive treatise, represents the agency's current thinking on a certain subject. A guidance document is not binding on the agency or the public. Such a document cannot itself be the basis for an enforcement action; there must be a violation of a statute or regulation. Similarly, a company affected by a guidance relating to premarket applications may use a method other than that set forth in the guidance if it can show that the alternate method satisfies the requirements of the applicable statute(s) and regulation(s).

The agency explicitly states that guidance is not binding in many of its guidance documents. Moreover, when FDA trains its employees, it instructs them that guidance documents are not binding. Nevertheless, some industry representatives say that industry feels bound by guidance documents and that FDA employees have not always been clear about the nature of such documents. Therefore, FDA plans to undertake a communication effort that will focus both on the language in guidance documents and on education of those who use and rely on guidance documents. With respect to guidance document language, the agency will take two steps. First, within each guidance document, FDA will explicitly state the principle that guidance is not binding. The language FDA has developed is:

> Although this guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, it does represent the agency's current thinking on ——.

Second, FDA will attempt to ensure that guidance documents use language that clearly conveys their nonbinding nature. Guidance documents should not use compulsory language such as ''shall'' and ''must,'' except when referring to a statutory or regulatory requirement. The agency currently reviews much of its newly issued guidance to ensure that it includes language such as that proposed above and that it excludes mandatory language. FDA plans to adopt internal procedures to ensure that such a review reaches all guidance documents. If it is determined that the agency should change the nomenclature of existing guidance, the agency will make any appropriate language changes to such guidance on the same schedule established for changing their titles. Otherwise, FDA will make any such language changes when the documents are substantively updated or revised. Regardless of when or whether appropriate language changes are made, existing guidance has the same nonbinding effect as newly issued guidance.

FDA believes that the language changes discussed above will serve to communicate the nonbinding nature of guidance. FDA also will develop an internal ''good guidance practices'' document that explicitly describes how the agency will use guidance. In addition, FDA will develop materials that accurately describe the legal effect of guidance to be used in internal FDA training programs. FDA believes that all of the internal efforts also should work to educate the public. Nevertheless, FDA would like to receive comments on additional ways to educate the public regarding guidance documents and their legal effect.[1]

C. Development/Public Input

The IMDMC petition argued that FDA should institute greater controls over the initiation, development, and issuance of guidance documents to assure the appropriate level of meaningful public participation. Although FDA recognizes the benefits of input from industry, consumer groups, and scientific experts and it increasingly solicits public input during guidance document development, FDA has not always been consistent in these respects. Therefore, the agency wants to implement consistent procedures for public input on its guidance documents.

As part of its effort to increase public participation in the guidance document process, FDA intends to develop an agency-wide practice to ensure that all of FDA's Centers and Offices are soliciting or accepting public input in connection with their guidance documents. The level of public input should allow the public opportunity to comment, but not be so extensive or prolonged that the burden and inherent delay make it too difficult for the agency to issue timely guidance. The IMDMC suggested that FDA adopt the Administrative Conference Recommendation 76–5, *Interpretive Rules of General Applicability and Statements of General Policy* (hereinafter referred to as the Recommendation). It is the agency's current judgment that such an approach is not practical.

The Recommendation would require FDA to use notice-and-comment rulemaking before promulgation of an ''interpretive rule of general applicability or a statement of policy which is likely to have a substantial impact on the public'' unless it makes a finding that it is ''impracticable, unnecessary, or contrary to the public interest'' to use such procedures (the Recommendation, ¶ 1). For other interpretive rules or policy statements, FDA would be required to invite the public to submit postpromulgation comments, unless such procedures would serve no public interest or would be so burdensome as to outweigh any foreseeable gain (the Recommendation, ¶ 2). FDA would be required to respond to such comments within a prescribed period of time.

The problems with this approach were articulated by FDA in the Federal Register of April 4, 1991 (56 FR 13757 at 13758), in the preamble to its final rule on amending § 10.40 (21 CFR 10.40). The substantial impact standard suggested by the Recommendation would invite litigation over virtually every agency decision to issue such rules (and statements) without engaging in informal rulemaking. Moreover, the courts have largely rejected that standard for determining whether a rule is subject to informal rulemaking. (See e.g., *American Hospital Ass'n.* v. *Bowen*, 834 F.2d 1037 (D.C. Cir. 1987); *Baylor University Medical Center* v. *Heckler*, 758 F.2d 1052 (5th Cir. 1985); *Alcaraz* v. *Block*, 746 F.2d 593 (9th Cir. 1984); *Levesque* v. *Block*, 723 F.2d 175 (1st Cir. 1983).) As to the proposed postpromulgation comment period, the approach suggested by the Recommendation would severely limit the agency's discretion and could require FDA to analyze and inevitably respond to comments on many matters of limited public interest. The burden of such requirements would exceed the benefits in most cases. Finally, FDA already has the option of following notice-and-comment rulemaking even where it is not required by the Administrative Procedure Act (§ 10.40(d)).

FDA must have flexibility as to what type of public input it solicits in connection with the development of guidance. There are certain documents that warrant greater or lesser input — the amount of public input should be tailored to the type of guidance document the agency is issuing.

One option would be to adopt a three-tiered system with each tier encompassing a different approach to public comment. For tier 1 documents, FDA would notify the public of its intent to issue a guidance and solicit comment before issuing that guidance. In addition, where appropriate (e.g., when complex scientific issues are raised), FDA might also hold a public meeting or workshop to discuss the guidance or could involve advisory committees in the development process. For tier 2 documents, FDA would notify the public after it issues the guidance and solicit comment at that time. For tier 3 documents, FDA would regularly notify the public of new guidance that recently has been issued and would not specifically solicit comment, but would accept comment. The approach to tier 3 documents is consistent with the principle that FDA is receptive to comments on all of its guidance documents—old and new— at any time. Under current practices, the public may comment on guidance using informal means (e.g., letters or telephone calls) or using the more formal procedures for petitioning or meeting and corresponding with FDA that are set forth in part 10 (21 CFR part 10) of FDA's regulations (see §§ 10.25, 10.30, and 10.65).

Under the three-tiered approach, comments received on the first two tiers of guidance documents would be submitted to a public docket and be available for public review. Comments regarding the third tier would be submitted directly to the Centers or Offices—either to a person or an office that has been identified on the guidance document. Regardless of the document tier, FDA would not be required to respond to each comment but FDA would make changes to the guidance if any comments convince the agency that such changes are appropriate.

Whether a guidance is placed into tier 1, 2, or 3 would depend on a number of factors. FDA would like to receive comment on the types of documents that the public believes should be placed into each of the three categories. FDA anticipates that tier 1 guidance would be guidance that represents a significant change, is novel or controversial, or raises complex issues about which FDA would like to have significant public input; tier 2 guidance would be guidance that merely states FDA's current practices or does not represent a significant or controversial change; tier 3 guidance would be guidance directed largely to FDA's own staff and that has a limited effect on the public.

The agency believes that an approach such as the three tiers described here would allow it to make public input genuinely meaningful. The agency does not want to make a commitment to extensive public participation in the

[1] In the Federal Register of October 15, 1992 (57 FR 47314), FDA proposed to amend §§ 10.85 and 10.90 (21 CFR 10.85 and 10.90), which address advisory opinions and guidelines, to delete the provisions that obligate the agency to follow advisory opinions and guidelines until they are amended or revoked (except in unusual situations involving immediate and significant danger to health). As set forth in the proposed rule, those provisions appear to be inconsistent with the general principle that Federal agencies may not be estopped from enforcing the law (see 57 FR 47314 at 47315). Although FDA has not yet issued a final rule, the agency plans to make final decisions on the 1992 proposal under that rulemaking.

development of large numbers of guidance documents and then find itself unable to fulfill its promise. In other words, FDA does not want to be in a position where it is unable to review comments or able only to perform a cursory review of comments. FDA is soliciting comment on the three-tiered approach. In addition to receiving comment on the types of documents that the public believes should be placed into each of the three tiers, FDA would like to hear whether the public believes that access to comments (i.e., by placing them on the public docket) is an important part of good guidance practices.

To make the three-tiered (or any other) approach to public participation meaningful, FDA has to enable the public to know when new guidance is available for comment. FDA would like to receive comment regarding the best way to achieve this. The agency believes that is it inefficient to issue a separate Federal Register document for each guidance. Such an approach has profound resource implications and would likely result in a backlog. FDA would like to receive comment on how or if it should use the Federal Register. FDA also would like to receive comment on alternate ways of notifying the public. For example, would it be sufficient (or perhaps better) if FDA announced the availability of new guidance on the World Wide Web/internet and/or in the trade press? Are there circumstances when it would be more appropriate to directly notify the interested public or trade associations by letter? If the three-tiered system is adopted, notification of the public could vary depending on the tier of the document at issue.

Thus far, this document has focused on the issue of soliciting input on guidance that the agency has decided it should issue. Another important part of public input relates to the public telling the agency when it believes guidance is needed and what it believes the agency's priorities should be in directing resources to guidance development. As set forth in this document, the public currently has a number of vehicles for making its views known. Interested persons can use the regulatory procedures for petitioning or meeting and corresponding with FDA (see §§ 10.25, 10.30, and 10.65). Alternatively, interested persons may simply write or call FDA to communicate the need for guidance. FDA also could use the Federal Register to remind the public that the agency is open to receiving ideas on new areas for guidance. FDA would like to receive comments on appropriate procedures for suggesting areas for guidance.

D. Dissemination/Availability to Public

Currently, the public can obtain lists of certain guidance documents from at least some of the Centers and Offices. As for the actual documents, the Centers for Drug Evaluation and Research (CDER), Biologics Evaluation and Research (CBER), and Devices and Radiological Health (CDRH) have FAX information systems through which the public can request copies of guidance documents to be sent by telecopy. CDRH also maintains an electronic docket through which subscribers can access their guidance documents. CBER is in the process of implementing a similar program. The Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) guidance documents are available directly from those Centers. Some CFSAN guidance is available on Prime Connection. CFSAN, CVM, CBER, and CDER are in the process of making their guidance available on the World Wide Web. The Office of Regulatory Affairs (ORA) makes its ''Guide to the inspection of * * *'' series available via a dial-in PC. A large number of FDA guidance documents are available through the National Technical Information Service (NTIS) or from the Government Printing Office. Finally, when new guidance is issued, the Centers and Offices often publish notices in the Federal Register and/or mail copies of the documents to the regulated industry, trade associations, and the interested public.

FDA intends to ensure that all current guidance documents are included on a list of guidance documents and that the public is aware that the list or lists exist. One option is to make the list or lists available electronically and on the established FAX information systems. FDA also could annually publish a list of guidance documents in the Federal Register. The electronic lists should be updated as new documents are developed or old documents are revised, but FDA also could update both the electronic and FAX systems at least quarterly.

As for obtaining the actual documents, FDA is seeking comment on the current systems that are in place (i.e., do the systems provide adequate access to guidance documents?). Moreover, is it feasible to rely principally on the FAX systems and electronic methods—such as the World Wide Web/internet—or are hard copy dockets necessary?[2] Even without a hard copy docket, the public could request hard copies. Nevertheless, FDA is concerned that significant reliance on electronic methods could leave some parts of the public without adequate access.

Finally, IMDMC has stated that affected parties do not always receive the most current version of guidance and that the public does not know when guidance is out of date. FDA will take steps to ensure that all guidance documents are dated and that superseded guidance is removed both from the lists of guidance and from the access systems. FDA also will explore ways of informing the public when existing guidance becomes obsolete.

E. Appeals

An effective appeals process assures the public that there will be full and fair reconsideration and review of how guidance is being applied. Such a process further protects against guidance documents being applied as binding requirements.

Under the general provisions set forth in part 10 of its regulations, FDA provides a number of vehicles that any person or firm may use to seek an appeal of an agency employee's decision. Pursuant to § 10.75, an interested person may request internal agency review of an agency decision made by anyone other than the Commissioner. Such review ordinarily would be by the employee's supervisor, but may move up the management chain to the Center Director or Commissioner's Office if the issue cannot be resolved, important policy matters are present, or it would be in the public interest. Sections 10.25 and 10.33 permit an interested person to petition the Commissioner to review any administrative action. This would permit a person or firm to petition the agency regarding guidance documents. The regulations also include less formal methods of appeal. For example, pursuant to § 10.65, an interested person may correspond or meet with FDA

[2] In the Federal Register of July 27, 1993 (58 FR 40150), CDRH implemented a 1-year pilot to test two methods of enhancing public access to agency documents—including guidance documents. Two dockets—a public (hard copy) docket and an electronic docket (discussed herein)—were established. Throughout the year, CDRH monitored the number of inquiries received on the two dockets. The hard copy docket received 100 document requests, while the electronic docket received 17,000 inquiries. In the Federal Register of February 7, 1995 (60 FR 7204), CDRH terminated the public (hard copy) docket because of its marginal utilization. The electronic docket was continued. (The CDRH FAX system, which is another means of obtaining hard copies of guidance documents, was not affected by this pilot program.)

about any matter under FDA's jurisdiction.

In addition, there are specific provisions and procedures that apply to or are used by the Centers. For example, FDA's new drug regulations provide procedures for dispute resolution regarding new drug applications. These procedures include informal meetings with the division reviewing the application, meetings with an ombudsman, and referrals to advisory committees (see § 314.103 (21 CFR 314.103)). The new drug regulations also provide the sponsor an opportunity for a hearing on the question of whether there are grounds for denying approval of the application (see § 314.110 (21 CFR 314.110)). CBER's review letters (''approvable'' and ''not approvable'') state the sponsor's options for appeal. Specifically, CBER's ''not approvable'' letter informs the sponsor that it may request a meeting with CBER to discuss the steps needed for approval or may request an opportunity for a hearing.

Finally, persons with concerns about the application of guidance documents may contact the FDA Office of the Chief Mediator and Ombudsman (the Ombudsman's Office). The Ombudsman's Office, which reports directly to the Commissioner, works on resolving issues and conflicts that arise in any FDA component. The Ombudsman's staff is available to discuss options, explain FDA's practices and procedures, and suggest approaches for resolution. When appropriate, the staff of the Ombudsman's Office may contact the FDA staff involved in the issue and mediate a dispute.

As the above discussion indicates, FDA already has a significant number of appeals mechanisms—all of which can be used by persons dissatisfied with how guidance is being applied. The agency recently established a working group to address the consistency and adequacy of dispute resolution processes across the agency and the effectiveness of education regarding the availability of such processes to industry. FDA is soliciting comment on whether the public is sufficiently aware of the appeals mechanisms that are in place and whether the public believes that the mechanisms are sufficient for appealing decisions relating to guidance documents. If the answer is that the mechanisms in place are not sufficient, FDA would like to hear why they are not and would like to receive suggestions on alternate methods or ways to improve our current procedures.

II. Summary of Issues for Comment

Sections I. A. through I. E. of this document set forth a number of issues about which the agency would like to receive public comment. A summary of those issues is set forth below:

(1) FDA is soliciting comment on the value of a standardized nomenclature for guidance documents. If a standardized nomenclature is desirable, FDA is soliciting comment on what that nomenclature should be and the best approach to take regarding the nomenclature of existing guidance.

(2) FDA is soliciting comment on how best to communicate to its own staff and to the public the principle that guidance is not binding.

(3) FDA is soliciting comment on the proposed three-tiered approach to public input (including comment on how to classify documents as tier 1, 2, or 3) and/or suggestions for alternatives to the three-tiered approach. FDA also wants to hear whether public access to comments should be included as a part of good guidance practices. Finally, FDA is soliciting comment regarding how FDA should notify the public of new guidance and how the public can notify FDA of the need for guidance.

(4) FDA is soliciting comment on the adequacy of its current guidance document access programs and suggestions for improving access to guidance documents.

(5) FDA is soliciting comment on whether the public is sufficiently aware of current appeals mechanisms and whether the mechanisms are sufficient for appealing decisions relating to guidance documents. If the current processes are not sufficient, FDA would like to hear why they are not and would like to receive suggestions on alternate methods or ways to improve the current procedures.

Interested persons may, on or before June 5, 1996, submit to the Dockets Management Branch (address above) written comments regarding this document. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 29, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–5344 Filed 3–6–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0200]

Regulatory Approach To Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction; FDA Commissioner's Roundtable; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a FDA Commissioner's roundtable public meeting on the regulatory approach to products comprised of living autologous cells manipulated ex vivo and intended for structural repair or reconstruction. The purpose of this meeting is to discuss FDA's current thinking on the regulatory approach of these products with respect to clinical and manufacturing issues, and to get input on the agency's tentative approach. The comments received to the Dockets Management Branch in response to an earlier hearing held on November 16 and 17, 1995, will also be discussed.

DATES: The Commissioner's roundtable public meeting will be held on Friday, March l5, l996, from 8 a.m. to 5 p.m.

ADDRESSES: The Commissioner's roundtable public meeting will be held at the Parklawn Bldg., 5600 Fishers Lane, third floor, conference rooms C and D, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Emma J. Knight, Office of Blood Research and Review (HFM–305), Center for Biologics Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0969. Those persons interested in attending this meeting should FAX their registration to Emma J. Knight, 30l–827–2844, or Jeanne White, 30l–827–0926, including name(s), affiliation, address, telephone and FAX numbers by March l3, 1996. There is no registration fee for this public meeting, but advance registration is required. Space is limited and all interested parties are encourage to register early.

SUPPLEMENTARY INFORMATION: The purpose of this public meeting is to interact with interested persons on the good manufacturing practice and clinical issues related to products comprised of living autologous cells manipulated ex vivo and intended for surgical repair or reconstruction, and to discuss FDA's approach to these issues. FDA will take this public discussion into consideration in reaching a final decision on the approach the agency will take.