products. In contrast, many somatic cell products are subject to premarket review and approval and to all other pertinent requirements, including provisions governing misbranding and adulteration. The agency is interested in information and views on the relative strengths and weaknesses of these approaches as they relate to the regulation of MAS cells. In particular, the agency is interested in the following:

(1) What are the advantages and disadvantages of an approach that would require premarket product approval?

(2) If premarket approval is not required, what would be the advantages and disadvantages of an approach that required licensing of each establishment involved in the processing of the material?

(3) If premarket product approval is required, what safety and efficacy information should the agency seek in a premarket submission? What issues are important in clinical trial design (e.g., efficacy measurements, endpoints)?

(4) What role should institutional review boards or other third party review organizations play in the oversight of these products?

(e) Autologous cells manipulated ex vivo for implantation for structural repair or reconstruction may involve intraoperative procedures to remove the cellular material from the patient, shipment of the cellular material to a distant site, processing of the material at that site, and the return of the processed material to the physician for implantation. In light of these practices, the agency seeks comment on the need for the following:

(1) Recordkeeping, to enable audits, tracking, or recall, if necessary;

(2) Precautions to help prevent errors and accidents, such as wrong-donor infusion, or potential infectious disease transmission;

(3) Process controls and validation, to help ensure the appropriate characterization of the product before, during and after processing;

(4) Labeling, to help ensure that users are adequately informed of uses and risks associated with the product;

(5) Current good manufacturing practices (CGMP's), to help ensure the consistency and control of the process and product;

(f) What amount of time should be allowed for compliance after adoption of new regulatory frameworks? Are there widely-practiced procedures, e.g., recordkeeping or other GMP's, that could be implemented sooner than others?

V. Current Regulatory Status of Pending and Approved Applications

This notice is not intended to affect the status of any approved or pending investigational or marketing application. Pending the hearing and its outcome, FDA does not at this time intend to actively regulate products comprised of human living autologous cells manipulated ex vivo and intended for implantation for structural repair or reconstruction.

The agency recommends that any facility that currently distributes or plans to distribute such products pending the outcome of this hearing use appropriate process controls and validation and adhere to current good manufacturing practices. Informed consent from the patient should be obtained, and labeling should be truthful and not misleading.

In addition, recordkeeping and tracking should be performed to facilitate the distribution of any appropriate information, and recall if indicated. To guard against transmission of infectious disease, the facilities should take precautions to prevent errors and accidents such as wrong-donor infusion.

VI. Outcome of the Hearing

After the hearing, FDA will consider the information presented at the hearing, all written comments submitted to the docket, and all other relevant information in determining the appropriate regulation of these products. As the agency has indicated, FDA will provide appropriate time for compliance with any regulatory requirements.

VII. Notice of Hearing Under 21 CFR Part 15

For the reasons stated above, the Commissioner of Food and Drugs is announcing that a public hearing will be held in accordance with 21 CFR part 15. The purpose of hearing is to solicit information and views, under § 15.1(a), from interested persons on the public health issues and concerns relating to regulation of products that are comprised of living autologous cells manipulated ex vivo and intended for implantation for structural repair or reconstruction, including repair or reconstruction of the source tissue.

Every effort will be made to accommodate each person who wants to participate in the public hearing. However, those who want to ensure participation in the hearing are encouraged to submit: (1) A written notice of participation containing the name, address, phone number, facsimile number, affiliation (if any), topic of the presentation, and approximate amount of time requested for the presentation; and (2) a brief description or outline of their presentation. The information should be submitted to the Dockets Management Branch (address above) by close of business on the date specified above. Interested persons attending the public hearing who did not request in advance an opportunity to make a presentation will have an opportunity to be heard as time permits and at the discretion of the presiding officer.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by letter, telephone, or facsimile, with the amount of time assigned to each person and the approximate time his or her presentation is scheduled to begin. A hearing schedule will be available at the hearing and will be filed with the Dockets Management Branch (address above).

In order to enable all interested persons to submit data, information, and views on this subject, the administrative record of the hearing will remain open until February 16, 1996. Any person may submit written comments to the Dockets Management Branch (address above) no later than February 16, 1996. The agency will consider these comments in formulating its conclusions. In formulating the appropriate regulatory framework for products involving MAS cells, the agency may also consider information that cannot be made public by the agency, e.g., confidential commercial information. The agency does not intend to respond to or summarize the comments received.

The presiding officer will be the Chief Mediator and Ombudsman. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Under § 15.30, the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer or members of the panel may question any person during or at the conclusion of the presentations.

Public hearings, including hearings under part 15, are subject to FDA's guideline on the policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205, representatives of electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). Orders for copies of the transcript can be placed at the meeting, or through the Dockets Management Branch (address above).