DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0169]

Combination Products Containing Live Cellular Components; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to discuss the jurisdictional classification, assignment, and premarket review of certain products that consist of living human cells in combination with a device matrix. The hearing will focus on products that are intended for wound healing (e.g., wound repair or skin regeneration, replacement, or reconstruction), although the information obtained may also be pertinent to questions concerning other combination products containing live cells. Combination products that include human cell or tissue components have significant potential to enhance the public health. The purpose of the hearing is to solicit information and views from interested persons, including scientists, clinical investigators, professional groups, trade groups, commercial enterprises, and consumers, on the issues and concerns relating to the premarket review and regulation of these combination products. To assist in the development of a consistent policy on jurisdiction for these products, FDA is interested in responses to specific questions and any other pertinent information stakeholders would like to share.

DATES: The public hearing will be held on Monday, June 24, 2002, from 9 a.m. to 5 p.m. Submit written or electronic notices of participation by June 14, 2002. Written comments will be accepted until August 23, 2002.

ADDRESSES: The public hearing will be held at the Double Tree Hotel, Plaza II and III, 1750 Rockville Pike, Rockville, MD 20852. Directions to the hotel can be found at www.doubletreerockville.com. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: FDADockets@oc.fda.gov. Submit electronic comments to http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. Transcripts of the hearing will be available for review at the Dockets Management Branch and on the Internet at http://www.fda.gov/ohrms/dockets.

FOR FURTHER INFORMATION CONTACT: Karen Wesley, Office of the Ombudsman, Office of Communications and Constituent Relations (HF–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390, FAX 301–480–8039, e-mail: ombuds@oc.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public hearing to discuss the jurisdictional classification, assignment, and premarket review of products that consist of living human cells in combination with a device matrix that are intended for wound healing. The meeting is another step in the agency's continuing effort to clarify and refine its regulatory approach to products that are comprised in whole or in part of living cells or tissues.

As the field of cell and tissue therapy has evolved, the agency has developed policies and practices to regulate these emerging products appropriately. For example, FDA is developing a risk-based regulatory approach for human cells, tissues, and cellular and tissue-based products (HCT/Ps). Under this approach, certain HCT/Ps would be subject to various requirements, including registration and listing, donor eligibility requirements, and good tissue practice requirements, but would not be subject to premarket review and approval. Other HCT/Ps, including combination products consisting of a cellular product combined with a device, would be subject to premarket review and approval.

Most cell therapies currently under development involve the use of cells alone, or in combination with biological products, such as cytokines or growth factors. However, in recent years sponsors have begun to combine human cells with other FDA-regulated articles, including devices or drug products. The combination of two distinct components that would normally be regulated under different regulatory authorities introduces additional factors to consider in the determination of primary jurisdiction and the application of appropriate regulatory authorities. In accordance with section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(1), the agency is required to assign primary jurisdiction for premarket review of combination products based on the product's ''primary mode of action.'' In order to determine a combination product's primary mode of action the agency must be able to identify how the product acts on the body and to determine the relative contribution of each of its component parts.

In the absence of clear scientific data demonstrating which mode of action is primary, other factors have been considered to determine assignment of review responsibility within FDA. Historically, these other factors have included the guidance provided by the intercenter agreements, determination of the most novel element or component with the greatest safety risk and indication for use. Many of these products have been characterized as ''cultured skin'' products or interactive wound dressings and have been reviewed and regulated by the Center for Devices and Radiological Health (CDRH) under medical device authorities. Several such products have gone through CDRH administered review and are now marketed under approved premarket approval applications. FDA is soliciting information to determine whether this class of products should be transferred to the Center for Biologics Evaluation and Research (CBER) for premarket review and regulation.

II. Purpose and Scope of the Hearing

The promise of combination products that use living cells in combination with a device matrix for wound healing may be significant. Because such products combine cell and non-cell components successful development and marketing of these products may be slowed by uncertainty about jurisdiction, particularly as it relates to the nature and scope of regulatory requirements that must be met in order to bring these products to market. Moreover, such products have increasingly been the subject of questions regarding both jurisdiction and pre and postmarket requirements. The agency recognizes that it may need to modify existing paradigms to address the unique characteristics of these combinations.

In light of the regulatory and scientific issues posed by such combination products, the agency is holding a public hearing to solicit: (1) Information about these products, (2) recommendations on the formulation and implementation of a consistent policy for product assignment, and (3) appropriate requirements for approval.

The hearing will focus on a discussion of combination products that consist of autologous or allogeneic living human cells combined with a device matrix for wound healing. The agency notes that some of the products

that consist of living cells combined with a device matrix intended for wound healing are now assigned to CDRH. Depending upon the information presented at the hearing, the agency could conclude that the primary mode of action of some or all of these products is that of the cell component, and that the product(s) should therefore be reassigned to CBER.

Single entity products, combination products containing bone, ligament and vascular products used for structural purposes, and drug-device combination products are beyond the scope of this hearing. In addition, the hearing will not consider products intended for purposes other than wound healing, such as encapsulated pancreatic cells intended for implantation to produce insulin to treat diabetes.

Combination products that contain a gene therapy component are also beyond the scope of this hearing. The term gene therapy includes all products that contain genetic material administered to modify or manipulate the expression of genetic material or to alter the biological properties of living cells.

III. Issues for Discussion

The agency recognizes the importance of promoting the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner, and of protecting the public health by assuring the safety and effectiveness of regulated medical products. New technologies and products that result from the combination of two distinct components provide not only unique scientific questions, but also challenges related to where and how the products should be regulated in order to ensure adequate, predictable, and consistent regulatory oversight. This public hearing is being held to discuss the classification, assignment, and premarket review of combination products comprised of live human cells used in combination with a device matrix for wound healing (e.g., wound repair, or skin regeneration, replacement or reconstruction). To assist in the development of a consistent policy on jurisdiction for these products, the agency invites information and comments on the following:

1. What are the public health concerns related to these combination products as a whole and with respect to their individual components? What information should the agency require in the premarket submission to demonstrate the safety and efficacy of combination products that contain live cells used in combination with a device matrix for wound healing (e.g., wound repair, or skin regeneration, replacement or reconstruction)? What regulatory requirements are necessary to ensure that adequate manufacturing controls are in place for both the device and live cell components? What other issues are important (e.g., clinical trial design, informed consent, infectious disease concerns)?

2. Given that primary mode of action determines jurisdiction for combination products, what information should the agency consider in identifying the level of contribution of each component to the therapeutic effect of the product? For example, skin replacement products are intended to act as wound coverings (historically considered a device action), and as mediators of tissue regeneration or repair by providing a living substrate to grow replacement tissue and through the production of soluble factors (historically considered to be biological product activities). What information should the agency consider in determining which action is primary?

3. In instances where both components of a combination product containing live cells appear to make a significant contribution to the therapeutic effect of the product and it is not possible to determine which mode of action is primary, what other factors should the agency consider in the assignment of primary jurisdiction? Is there a clear hierarchy among these additional factors that should be observed in order to ensure an adequate review? Should these same factors be used to determine the appropriate type of premarket application?

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner's designee, the Senior Associate Commissioner for Communications and Constituent Relations. The presiding officer will be accompanied by senior management from CBER, CDRH, and the Center for Drug Evaluation and Research (CDER).

Persons who wish to participate in the part 15 hearing must file a written or electronic notice of participation with the Dockets Management Branch (see **ADDRESSES**) before June 14, 2002. To ensure timely handling, any outer envelope should be clearly marked with the docket number listed at the head of this notice along with the statement ''Combination Products Containing Live Cellular Components Hearing.'' Groups should submit two written copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; a brief summary of the presentation; and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. If time permits, FDA may allow interested persons attending the hearing who did not submit a written or electronic notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Dockets Management Branch under the docket number listed at the head of this document.

Under § 15.30(f), 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 and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the 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). The transcript of the hearing will be available on the Internet at http://www.fda.gov/ohrms/dockets, and orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (see **ADDRESSES**).

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this notice acts as a

waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic notices of participation and comments for consideration at the hearing by June 14, 2002. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until August 23, 2002. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (see **ADDRESSES**) by August 23, 2002. Two copies of any written 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain more information about this hearing or combination products in general at http://www.fda.gov.

Dated: April 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12171 Filed 5–10–02; 4:33 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Survey of Characteristics and Funding of School Mental Health Services: 2002–2003—New—SAMHSA's Center for Mental Health Services will sponsor this national study of the mental health services provided in U.S. public schools. A substantial proportion of public schools provide some level of mental health screening, prevention, and treatment services to their students. However, no national-level data are available on these services. The study is designed to document the types of mental health problems encountered in schools, the mental health services provided, the types and of qualifications of staff providing the services, the arrangements for delivery of services, and the funding of those services. The study will examine the prevalence of these mental health resources and their distribution across schools in the nation as they vary by grade level, size, locale, and the student populations served.

The survey will be conducted as a self-administered mail survey (with telephone followup) of a nationally representative sample of 2,000 public elementary, middle and secondary schools. The districts associated with the sampled schools will be asked to answer questions about funding sources, budgets, and issues related to funding. The results of the study will be available in the summer of 2003. Response burden for the survey is summarized in the following table.

Questionnaire	Number of respondents	Responses/ respondent	Burden/ response (hrs.)	Total burden hours
School district	1,200	1	.5	600
School	2,000	1	1.0	2,000
Total	3,200			2,600

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 8, 2002.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 02–12088 Filed 5–14–02; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Indian Arts and Crafts Board

Proposed Information Collection to Identify Tribal Non-Member Indian Artisan Certification Programs

AGENCY: Indian Arts and Crafts Board, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Arts and Crafts Board (IACB) is announcing its intention to request approval for the collection of information from those federally recognized Indian tribes that have established a non-member Indian artisan certification program as described in Pub. L. 101–644. This request for information from the tribes has been forwarded to the Office of Management and Budget (OMB) for review and comment. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collections but may respond after 30 days. Therefore, public comments should be submitted to OMB by June 14, 2002, in order to be assured of consideration.