

be purchased in order to perform such function(s).

Part IV of the proposed order provides that, for up to 120 days after service of the order, respondent may continue to ship products from existing stock in packaging with nonconforming labeling, as long as the packaging was printed less than 30 days after the date respondent signed the consent agreement.

Parts VI through IX require Palm to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part X provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 02-5968 Filed 3-12-02; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Human Research Protections Advisory Committee (NHRPAC)

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office for Human Research Protections.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Human Research Protections Advisory Committee (NHRPAC).

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below. Individuals planning on attending the meeting and who want to ask questions must submit their requests in writing in advance of the meeting to the contact person listed below.

DATES: The Committee will hold its next meeting on April 29-30, 2002. The

meeting will convene EST from 8:30 a.m. to its recess at approximately 5:30 p.m. on April 29 and resume at 8:30 a.m. to 5 p.m. on April 30.

ADDRESSES: Hyatt Regency Bethesda Hotel, One Bethesda Metro, Bethesda, MD, (301) 657-1234.

FOR FURTHER INFORMATION CONTACT: Keisha Johnson, Program Assistant, National Human Research Protections Advisory Committee, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852, (301) 435-4917. The electronic mail address is: kjohnson@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION: The National Human Research Protections Advisory Committee was established on June 6, 2000, to provide expert advice and recommendations to the Secretary of HHS, Assistant Secretary for Health, the Director, Office for Human Research Protections, and other departmental officials on a broad range of issues and topics pertaining to or associated with the protection of human research subjects.

Information about NHRPAC, and the draft agenda for the Committee's April 2002 meeting, will be posted on the NHRPAC website at: <http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm>.

Dated: March 7, 2002.

Greg Koski,

Executive Secretary, National Human Research Protections Advisory Committee.

[FR Doc. 02-5925 Filed 3-12-02; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0437]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; New Animal Drugs for Investigational Use; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 14, 2002 (67 FR 1772). The document announced that a proposed collection of information had been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The

document was published with an incorrect OMB control number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Doris Tucker, Office of Policy, Planning, and Legislation (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 02-855, appearing on page 1772 in the **Federal Register** of Monday, January 14, 2002, the following correction is made:

1. On page 1772, in the second column, in the fourteenth line, "0910-0017" is corrected to read "0910-0117".

Dated: March 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-5922 Filed 3-12-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0073]

"Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation" dated March 2002. The guidance document is intended to remind all tissue establishments that the current requirement to prepare, validate, and follow procedures to prevent infectious disease contamination or cross-contamination during the processing of human tissues intended for transplantation includes such infectious disease agents as viruses, bacteria, fungi, and will include transmissible spongiform encephalopathy (TSE)-associated prions as technology progresses.

DATES: General comments on agency guidance documents are welcome at any time. The agency is soliciting public comment, but is implementing this guidance document immediately because of public health concerns. FDA is requesting that you submit with your comments any information on specific methods currently used by tissue establishments to prevent infectious disease contamination and cross-

contamination of tissue during processing.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written or electronic comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation" dated March 2002. The document is intended to remind all tissue establishments that the current requirement to prepare, validate, and follow procedures to prevent infectious disease contamination or cross-contamination during the processing of human tissues intended for transplantation (21 CFR 1270.31(d)) includes such infectious disease agents as viruses, bacteria, fungi, and will include TSE-associated prions as technology progresses. Current regulations for human tissue intended for transplantation are found in 21 CFR parts 1270 and 1271.

This guidance is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on the validation of procedures for processing of human tissues intended for transplantation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be

used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The agency is soliciting public comment, but is implementing this guidance document immediately because of the public health concerns related to the possible risk of infectious disease contamination or cross-contamination during tissue processing. In particular, FDA's concern is heightened by recent reports from the Centers for Disease Control and Prevention about bacterial contamination of musculoskeletal allografts associated with injury as well as death in recipients of these tissues [MMWR; 50(46): 1035-1036, November 23, 2001; 50(48): 1080-1083, December 7, 2001.] FDA is requesting that you submit with your comments any information on specific methods currently used by tissue establishments to prevent infectious disease contamination and cross-contamination of tissue during processing. FDA plans to have further public discussion on this issue and to develop additional guidance containing more specific recommendations on validation methods for tissues in the future.

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 4, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.
[FR Doc. 02-5963 Filed 3-12-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: October 2001

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 2001, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
ABRANTE, HECTOR HIALEAH, FL	02/20/2002
ADAMS, BILLY WAYNE FEDERAL WAY, WA	02/20/2002
BINA, SHOKROLLAH LOS ANGELES, CA	02/20/2002
CARING RESPIRATORY SVCS, INC CORAL GABLES, FL	09/17/2001
CARROLL, MAXIE G TALLAHASSEE, FL	02/20/2002
CORVO, RENE JESSUP, GA	02/20/2002
DJGLYAN, ARUTYUN ELOY, AZ	02/20/2002
DOUGHERTY, TERENCE W CLAYTON, MO	02/20/2002
ENRIQUEZ, HONORIA MIAMI, FL	02/20/2002
ESPINOZA, THELMA AUXILIADOR SOUTHGATE, CA	02/20/2002
FAULKNER, THERESA ANN ... PHOENIX, AZ	02/20/2002
FRENZI, MICHELLE L AURORA, CO	02/20/2002
FULLER, ALISHA ANN SPRINGFIELD, OR	02/20/2002
HING, VAN DAN	02/20/2002