

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5347]

Draft "Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Intimate Contacts;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Intimate Contacts" dated February 2002. The draft guidance document provides recommendations to all registered blood and plasma establishments, and establishments engaged in manufacturing plasma derivatives. The draft guidance document, when finalized, is intended to provide recommendations regarding the disposition of blood products manufactured from a donor who is retrospectively discovered to have received a xenotransplantation product or to have been an intimate contact of a xenotransplantation product recipient. This is the second draft guidance document and it incorporates revisions based on public comments received on the first draft guidance document by the same name announced in the **Federal Register** of December 30, 1999 (64 FR 73562).

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by May 13, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the 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:

Michael D. Anderson, 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 revised, second draft document entitled "Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Intimate Contacts" dated February 2002. The draft guidance document provides FDA's recommendations to all registered blood and plasma establishments, and establishments engaged in manufacturing plasma derivatives. The draft guidance document, when finalized, is intended to provide recommendations regarding the disposition of blood products manufactured from a donor who is retrospectively discovered to have received a xenotransplantation product or to have been an intimate contact of a xenotransplantation product recipient. This second draft guidance document incorporates revisions based on public comments received on the first draft document by the same name announced in the **Federal Register** of December 30, 1999, due to the number of changes made to the previous version of the draft guidance.

FDA issues this draft guidance consistent with the good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on precautionary measures to reduce the possible risk of transmission of zoonoses by xenotransplantation product recipients and their contacts, through blood and blood products. 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

FDA is distributing this draft document for comment purposes only and does not intend to implement the draft guidance at this time. To ensure adequate consideration in preparation of the final document, interested persons may submit written comments to the Dockets Management Branch (address above) by May 13, 2002. Submit two copies of any comments, 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 <http://www.fda.gov/cber/guidelines.htm>.

Dated: January 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-3200 Filed 2-8-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4728-N-01]

Notice of Certain Operating Cost Adjustment Factors for Fiscal Year 2002

AGENCY: Office of the Secretary, HUD.

ACTION: Publication of Fiscal Year (FY) 2002 Operating Cost Adjustment Factors (OCAFs) for Section 8 rent adjustments at contract renewal under section 524 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA), as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of 1999, and under the Low-Income Housing Preservation and Resident Homeownership Act of 1990 (LIHPRA) Projects assisted with Section 8 Housing Assistance Payments.

SUMMARY: This notice establishes factors used in calculating rent adjustments under section 524 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA) as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of

1999, and under the Low-Income Housing Preservation and Resident Homeownership Act of 1990 (LIHPHA).

EFFECTIVE DATE: February 11, 2002.

FOR FURTHER INFORMATION CONTACT: Regina Aleksiewicz, Housing Project Manager, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, Office of Multifamily Housing, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708-3000; extension 2600 (This is not a toll-free number). Hearing-or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Operating Cost Adjustment Factors (OCAFs)

Section 514(e)(2) of the FY 1998 HUD Appropriations Act, requires HUD to establish guidelines for rent adjustments based on an operating cost adjustment factor (OCAF). The legislation requiring HUD to establish OCAFs for LIHPHA projects and projects with contract renewals under section 524 of MAHRA is similar in wording and intent. HUD has therefore developed a single factor to be applied uniformly to all projects utilizing OCAFs as the method by which rents are adjusted.

Additionally, section 524 of the Act gives HUD broad discretion in setting OCAFs—referring simply to “operating cost factors established by the Secretary.” The sole exception to this grant of authority is a specific requirement that application of an OCAF shall not result in a negative rent adjustment. OCAFs are to be applied uniformly to all projects utilizing OCAFs as the method by which rents are adjusted upon expiration of the term of the contract. OCAFs are applied to project contract rent less debt service.

An analysis of cost data for FHA-insured projects showed that their operating expenses could be grouped into nine categories: Wages, employee benefits, property taxes, insurance, supplies and equipment, fuel oil, electricity, natural gas, and water and sewer. Based on an analysis of these data, HUD derived estimates of the percentage of routine operating costs that were attributable to each of these nine expense categories. Data for projects with unusually high or low expenses due to unusual circumstances were deleted from analysis.

States are the lowest level of geographical aggregation at which there are enough projects to permit statistical

analysis. Additionally, no data were available for the Western Pacific Islands. Data for Hawaii was therefore used to generate OCAFs for these areas.

The best current measures of cost changes for the nine cost categories were selected. The only categories for which current data are available at the State level are for fuel oil, electricity, and natural gas. Current price change indices for the other six categories are only available at the national level. The Department had the choice of using dated State-level data or relatively current national data. It opted to use national data rather than data that would be two or more years older (*e.g.*, the most current local wage data are for 1996). The data sources for the nine cost indicators selected used were as follows:

Labor Costs—6/00 to 6/01 Bureau of Labor Statistics (BLS), “Employment Cost Index, Private Sector Wages and Salaries Component at the National Level.”

Employment Benefit Costs—6/00 to 6/01 (BLS), “Employment Cost Index, Employee Benefits at the National Level.”

Property Taxes—6/00 to 6/01 (BLS), “Consumer Price Index, All Items Index.”

Goods, Supplies, Equipment—6/00 to 6/01 (BLS), “Producer Price Index, Finished Goods Less Food and Energy.”

Insurance—6/00 to 6/01 (BLS), “Consumer Price Index, Residential Insurance Index.”

Fuel Oil—Energy Information Agency, Petroleum Marketing Annual 2000, Table 18, “Prices of No.2 Distillate to Residents by PAD District and Selected States,” (Petroleum Administration for Defense District (PADD) average changes were used for the States with too little fuel oil consumption to have values.)

Electricity—Energy Information Agency, Electric Power Annual Volume 1, 2000, Table 22 “Retail Sales of Electricity, Revenue and Average Revenue per Kilowatt-hour (and RSEs) by U.S. Electric Utilities to Ultimate Consumers by Census Division and State, 1999–2000—Residential.”

Natural Gas—Energy Information Agency, Natural Gas Annual, 2000, Table 22, “Average Price of Natural Gas Delivered to Residential Consumers by State, 1996–2000 (Preliminary).”

Water and Sewer—6/00 to 6/01, (BLS), “Consumer Price Index—Detailed Report.”

The sum of the nine cost components equals 100 percent of operating costs for purposes of OCAF calculations. To calculate the OCAFs, the selected inflation factors are multiplied by the

relevant State-level operating cost percentages derived from the previously referenced analysis of FHA insured projects. For instance, if wages in Virginia comprised 50 percent of total operating cost expenses and wages increased by 4 percent from June 2000 to June 2001, the wage increase component of the Virginia OCAF for FY 2002 would be 2.0 percent ($4\% \times 50\%$). This 2.0 percent would then be added to the increases for the other eight expense categories to calculate the FY 2001 OCAF for Virginia. These types of calculations were made for each State for each of the nine cost components, and are included as the Appendix to this Notice.

II. MAHRA and LIHPHA OCAF Procedures

The Multifamily Assisted Housing Reform and Affordability Act of 1997 (title V of Pub. L. 105–65, approved October 7, 1997; 42 U.S.C. 1437f note (MAHRA)) as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of 1999, created the Mark-to-Market Program to reduce the cost of Federal housing assistance, enhance HUD’s administration of such assistance, and to ensure the continued affordability of units in certain multifamily housing projects. Section 524 of MAHRA authorizes renewal of Section 8 project-based assistance contracts for projects without Restructuring Plans under the Mark-to-Market Program, including renewals that are not eligible for Plans and those for which the owner does not request Plans. Renewals must be at rents not exceeding comparable market rents except for certain projects. For Section 8 Moderate Rehabilitation projects, other than single room occupancy projects (SROs) under the Stewart B. McKinney Homeless Assistance Act (McKinney Act, 42 U.S.C. 11301 *et seq.*), that are eligible for renewal under section 524(b)(3) of MAHRA, the renewal rents are required to be set at the lesser of: (1) The existing rents under the expiring contract, as adjusted by the OCAF; (2) fair market rents (less any amounts allowed for tenant-purchased utilities; or (3) comparable market rents for the market area.

The Low-Income Housing Preservation and Resident Homeownership Act of 1990 (LIHPHA) (see, in particular, section 222(a)(2)(G)(i) of LIHPHA, 12 U.S.C. 4112(a)(2)(G) and the regulations at 24 CFR 248.145(a)(9)) requires that future rent adjustments for LIHPHA projects be made by applying an annual factor to be determined by the Secretary to the

portion of project rent attributable to operating expenses for the project and, where the owner is a priority purchaser, to the portion of project rent attributable to project oversight costs.

III. Findings and Certifications

Environmental Impact

This issuance sets forth rate determinations and related external administrative requirements and procedures that do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number for this program is 14.187.

Dated: February 4, 2002.

Mel Martinez,
Secretary.

Appendix—FY 2002 Operating Cost Adjustment Factors

State	FY 2002 OCAF (percent)
ALABAMA	3.6
ALASKA	5.1
ARIZONA	2.6
ARKANSAS	3.5
CALIFORNIA	4.0
COLORADO	3.7
CONNECTICUT	4.7
DELAWARE	3.6
DIST. OF COLUMBIA	4.0
FLORIDA	3.6
GEORGIA	7.2
HAWAII	5.1
IDAHO	3.6
ILLINOIS	5.0
INDIANA	4.1
IOWA	4.4
KANSAS	4.4
KENTUCKY	4.0
LOUISIANA	4.5
MAINE	5.3
MARYLAND	3.7
MASSACHUSETTS	4.7
MICHIGAN	3.2
MINNESOTA	5.6
MISSISSIPPI	4.1
MISSOURI	4.0
MONTANA	2.8
NEBRASKA	4.1

State	FY 2002 OCAF (percent)
NEVADA	3.2
NEW HAMPSHIRE	5.2
NEW JERSEY	3.5
NEW MEXICO	5.2
NEW YORK	5.0
N. CAROLINA	3.5
N. DAKOTA	4.3
OHIO	4.0
OKLAHOMA	4.7
OREGON	3.7
PENNSYLVANIA	2.9
RHODE ISLAND	5.4
S. CAROLINA	3.5
S. DAKOTA	5.2
TENNESSEE	3.4
TEXAS	4.7
UTAH	3.9
VERMONT	4.6
VIRGINIA	2.9
WASHINGTON	3.6
W. VIRGINIA	3.3
WISCONSIN	4.2
WYOMING	5.9
PACIFIC ISLANDS	3.8
PUERTO RICO	3.6
VIRGIN ISLANDS	3.4
U.S. AVERAGE	4.2

[FR Doc. 02-3221 Filed 2-8-02; 8:45 am]

BILLING CODE 4210-27-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Bureau of Indian Affairs, Office of Special Trustee for American Indians, Office of Indian Trust Transition; Tribal Consultation on Indian Trust Asset Management

AGENCY: Office of the Secretary, Bureau of Indian Affairs, Office of the Special Trustee for American Indians, Office of Indian Trust Transition, Interior.

ACTION: Notice; correction.

SUMMARY: The Office of the Secretary, Bureau of Indian Affairs, Office of the Special Trustee for American Indians, and the Office of Indian Trust Transition gave public notice in the **Federal Register** of January 31, 2002, (67 FR 4703) of a tribal consultation meeting in Portland, Oregon, to be held on February 14, 2002. The time of the consultation meeting was in error. This action corrects that error.

FOR FURTHER INFORMATION CONTACT: Wayne R. Smith, Deputy Assistant

Secretary—Indian Affairs, 1849 C Street, NW, MS 4240 MIB, Washington, DC 20240 (202/208-7163).

SUPPLEMENTARY INFORMATION: In the **Federal Register** document published on January 31, 2002, there was an error in the scheduled time of the consultation meeting. The Department is correcting the document as follows:

In notice document (**Federal Register** document 02-2303) make the following correction:

On page 4730, in the third column, 16 lines from the bottom of the column, the time for the consultation meeting should read "1:00 p.m."

Dated: February 6, 2002.

J. Steven Griles,

Deputy Secretary.

[FR Doc. 02-3283 Filed 2-8-02; 8:45 am]

BILLING CODE 4310-02-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife, Interior.

ACTION: Notice of permits issued.

SUMMARY: This notice contains a list of Recovery Permits issued under the Endangered Species Act in Region 2 of the Fish and Wildlife Service (Arizona, New Mexico, Oklahoma, and Texas) during 2001.

FOR FURTHER INFORMATION CONTACT: U.S. Fish and Wildlife Service, Chief, Endangered Species Division, Ecological Services, P. O. Box 1306, Room 4102, Albuquerque, New Mexico 87103; (505) 248-6649; (505) 248-6788.

SUPPLEMENTARY INFORMATION: Notice is hereby given that Region 2 of the U.S. Fish and Wildlife Service has issued the following permits, between January 1, 2001, and December 31, 2001, for scientific purposes, enhancement of propagation or survival, or interstate commerce of endangered species from applications duly received according to section 10(a)(1)(A) of the Endangered Species Act of 1973 (Act), as amended. Each permit issued was granted only after it was determined to be applied for in good faith, and that it was consistent with the Act and applicable regulations.

Permittee	Permit No.	Issuance Date
Dennis P. Humphrey	TE035179	01/03/01
ECO Plan Associates, Inc	TE830213	01/03/01
Westland Resources, Inc	TE834782	01/03/01
Lockheed Martin Environmental Services	TE025197	01/03/01