in PDUFA II fees than Congress appropriated.

FDA also has requests for waivers or reductions of FY 1998 fees pending. For this reason FDA is not reducing its FY 2002 fees to offset excess collections at this time. An offset will be considered in a future year, if FDA still has collections in excess of appropriations for FY 1998 after the pending requests for FY 1998 waivers and reductions have been resolved.

V. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2001, the establishment fee was based on an estimate of 347 establishments subject to fees. For FY 2001, 379 establishments qualified for and were billed for establishment fees, before all decisions on requests for waivers or reductions were made. FDA estimates that a total of 25 establishment fee waivers or reductions will be made for FY 2001, for a net of 354 fee-paying establishments, and will use this number for its FY 2002 estimate of establishments paying fees, after taking waivers and reductions into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($49,598,556), by the estimated 354 establishments, for an establishment fee rate for FY 2002 of $140,109 (rounded to the nearest dollar).

B. Product Fees

At the beginning of FY 2001, the product fee was based on an estimate that 2,314 products would be subject to product fees. By the end of FY 2001, 2,348 products qualified and were billed for product fees before all decisions on requests for waivers or reductions were made. Assuming that there will be about 55 waivers and reductions made, FDA estimates that 2,293 products will qualify for product fees in FY 2002, after allowing for waivers and reductions, and will use this number for its FY 2002 estimate. Accordingly, the FY 2002 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($49,598,556) by the estimated 2,293 products for a product fee rate of $21,630 (rounded to the nearest dollar).

VI. Adjusted Fee Schedule for FY 2002

The fee rates for FY 2002 are set out in table 2 of this document:

TABLE 2.

Fee Category	Fee Rates for FY 2002
Applications	
Requiring clinical data	$313,320
Not requiring clinical data	$156,660
Supplements requiring clinical data	$156,660
Establishments	$140,109
Products	$21,630

VII. Implementation of Adjusted Fee Schedule

A. Application Fees

Any application or supplement subject to fees under PDUFA II that is submitted after January 16, 2002, must be accompanied by the appropriate application fee established in the new fee schedule. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee ID number on your check. Your check can be mailed to: Food and Drug Administration, P.O. Box 360909, Pittsburgh, PA 15251–6909.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Food and Drug Administration (360909), Mellon Client Service Center, rm. 670, 500 Ross St., Pittsburgh, PA 15262–0001. (Note: This Mellon Bank Address is for courier delivery only.)

Please make sure that the FDA P.O. Box number (P.O. Box 360909) is on the enclosed check.

FDA will bill applicants who submitted lower application fees from October 1 to January 16, 2002, for the difference between the amount they submitted and the amount specified in the Adjusted Fee Schedule for FY 2002.

B. Establishment and Product Fees

By [*insert date of publication in the* **Federal Register**], FDA will issue invoices for establishment and product fees for FY 2002 under the new Adjusted Fee Schedule. Payment will be due by January 31, 2002. FDA will issue invoices for any products and establishments subject to fees for FY 2002 that qualify for fees after the January 2002 billing.

Dated: January 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–1068 Filed 1–11–02; 2:57 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0318]

''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products'' dated January 2002. The new recommendations are intended to minimize the possible risk of CJD and vCJD transmission from blood and blood products. The guidance document provides comprehensive current recommendations to all registered blood and plasma establishments for deferral of donors with possible exposure to the agent of vCJD. The guidance document announced in this notice finalizes the draft guidance of the same title, dated August 2001, and supersedes the guidance document entitled ''Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products'' dated November 1999.

DATES: Submit written or electronic comments on agency guidance documents at any time.

ADDRESSES: Submit written requests for single copies of this 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 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: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products'' dated January 2002. This guidance document contains comprehensive revised recommendations based upon advisory committee discussions, internal Public Health Service and FDA deliberations, and public comments. FDA has developed recommendations for donor deferral, and product retrieval, quarantine, and disposition based upon consideration of risk in the donor and product, and the effect that withdrawals and deferrals might have on the supply of life- and health-sustaining blood components and plasma derivatives. The new recommendations are intended to minimize the possible risk of CJD and vCJD transmission from blood products while maintaining their availability. The guidance document announced in this notice finalizes the draft guidance of the same title, dated August 2001, announced in the **Federal Register** of August 29, 2001 (66 FR 45683). The guidance document also supersedes the guidance document entitled ''Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products'' dated November 1999 (64 FR 65715, November 23, 1999).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. 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

Interested persons may, at any time, submit written 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: January 7, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–1026 Filed 1–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4739–N–01]

Notice of Proposed Information Collection: Comment Request; Land Sales Registration, Purchaser's Revocation Rights, Sales Practices and Standards, and Formal Procedures and Rules of Practice

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 18, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Ivy Jackson, Acting Director, Interstate Land Sales/RESPA Division, Office of Consumer and Regulatory Affairs, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone (202) 708–0502 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Land Registration, Purchaser's Revocation Rights, Sales Practices and Standards, and Formal Procedures and Rules of Practice.

OMB Control Number, if applicable: 2502–0243.

Description of the need for the information and proposed use: The Interstate Land Sales Full Disclosure Act protects consumers from fraud in the sale of land by requiring developers of non-exempt subdivisions to register with HUD and give purchasers a