a. The agency or any component thereof; or

b. Any employee of the agency in his or her official capacity; or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

d. The United States Government; is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

7. To CMS or state contractors, to administer some aspect of the health benefits programs, or to a CMS grantee or program which is or could be affected by fraud and abuse, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in such programs.

8. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States, including any State or Local government agency, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in health benefits program funded in whole or in part by Federal funds.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on paper or electronic media.

RETRIEVABILITY:

Beneficiary's name, Medicaid identification number, Health Insurance Claim Number, Social Security Number or other identifying variables retrieve the records.

SAFEGUARDS:

CMS has safeguards for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and systems security requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, CMS has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the CMS system. For computerized records, safeguards have been established in accordance with HHS standards and National Institute of Standards and Technology guidelines; e.g., security codes will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resource Management (IRM) Circular #10, Automated Information Systems Security Program; CMS Information Systems Security, Standards Guidelines Handbook and OMB Circular No. A–130 (revised) Appendix III.

RETENTION AND DISPOSAL:

CMS and the repository of the National Archive and Records Administration (NARA) will retain identifiable EMRD data permanently, or as an indefinite retention.

SYSTEM MANAGER AND ADDRESS:

CMS, Director, Office of Strategic Planning, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, health insurance claim number, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), address, age, and sex, and social security number (SSN) (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR part 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR part 5b.7.)

RECORD SOURCE CATEGORIES:

Sources of information contained in this records system are expected to include: State Medicaid Management Information Systems, managed care organizations (i.e., encounter data), fee-for-service providers, surveys of demonstration participants or providers and comparison group members, medical records, Social Security Administration data bases, vital statistics and other relevant data systems.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 02–1063 Filed 1–15–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2002. The Prescription Drug User Fee Act of 1992 (PDUFA), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Fees for applications for FY 2002 were set by PDUFA, as amended, subject to adjustment for inflation. Total application fee revenues fluctuate with the number of fee-paying applications FDA receives. Fees for establishments and products are calculated so that total revenues from each category will approximate FDA's estimate of the revenues to be derived from applications.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management and Systems (HFA–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

PDUFA (Public Law 102–571), as amended by FDAMA (Public Law 105–

115), referred to as PDUFA II in this document, establishes three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)).

For FY 1998 through 2002, under PDUFA II, the application fee rates are set in the statute, but are to be adjusted annually for cumulative inflation since FY 1997. Total application fee revenues are structured to increase or decrease each year as the number of fee-paying applications submitted to FDA increases or decreases.

Each year from FY 1998 through 2002, FDA is required to set establishment fees and product fees so that the estimated total fee revenue from each of these two categories will equal the total revenue FDA expects to collect from application fees that year. This procedure continues the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fees: Application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 2002 for application, establishment, and product fees. These fees are retroactive to October 1, 2001, and will remain in effect through September 30, 2002. For fees already paid on applications and supplements submitted on or after October 1, 2001, FDA will bill applicants for the difference between fees paid and fees due under the new fee schedule. For applications and supplements submitted after January 16, 2002, the new fee schedule must be used. Invoices for establishment and product fees for FY 2002 will be issued in January 2002, using the new fee schedule.

II. Inflation and Workload Adjustment Process

PDUFA II provides that fee rates for each FY shall be adjusted by notice in the **Federal Register**. The adjustment must reflect the greater of : (1) The total percentage change that occurred during the preceding FY in the Consumer Price Index (CPI) (all items; U.S. city average), or (2) the total percentage pay change for that FY for Federal employees stationed in the Washington, DC metropolitan area. PDUFA II provides for this annual adjustment to be cumulative and compounded annually after 1997 (see 21 U.S.C. 379h(c)(1)).

PDUFA II also structures the total application fee revenue to increase or decrease each year as the number of fee-paying applications submitted to FDA increases or decreases. This provision allows revenues to rise or fall as this portion of FDA's workload rises or falls. To implement this provision, each year FDA will estimate the number of fee-paying applications it anticipates receiving. The number of applications estimated will then be multiplied by the inflation-adjusted statutory application fee. This calculation will produce the FDA estimate of total application fee revenues to be received.

PDUFA II also provides that FDA shall adjust the rates for establishment and product fees so that the total revenues from each of these categories is projected to equal the revenues FDA expects to collect from application fees that year. PDUFA II provides that the new fee rates based on these calculations be adjusted within 60 days after the end of each FY (21 U.S.C. 379h(c)(2)).

III. Inflation Adjustment and Estimate of Total Application Fee Revenue

PDUFA II provides that the application fee rates set out in the statute be adjusted each year for cumulative inflation since 1997. It also provides for total application fee revenues to increase or decrease based on increases or decreases in the number of fee-paying applications submitted.

A. Inflation Adjustment to Application Fees

Application fees are assessed at different rates for qualifying applications depending on whether the applications require clinical data for safety or effectiveness (other than bioavailability or bioequivalence studies) (21 U.S.C. 379h(a)(1)(A) and 379h(b)). Applications that require clinical data are subject to the full application fee. Applications that do not require clinical data and supplements that require clinical data are assessed one-half the fee of applications that require clinical data. If FDA refuses to file an application or supplement, 75 percent of the application fee is refunded to the applicant (21 U.S.C. 379h(a)(1)(D)).

The application fees described above are set out in PDUFA II for FY 2002 ($258,451 for applications requiring clinical data, and $129,226 for applications not requiring clinical data or supplements requiring clinical data) (21 U.S.C. 379h(b)(1)), but must be adjusted for cumulative inflation since 1997. That adjustment each year is to be the greater of: (1) The total percentage change that occurred during the preceding FY in the CPI, or (2) the total percentage pay change for that FY for Federal employees stationed in the Washington, DC metropolitan area, as adjusted for any locality-based payment. PDUFA II provides for this annual adjustment to be cumulative and compounded annually after 1997 (see 21 U.S.C. 379h(c)).

The adjustment for FY 1998 was 2.45 percent (62 FR 64849, December 9, 1997). This was the greater of the CPI increase for FY 1997 (2.15 percent) or the increase in applicable Federal salaries (2.45 percent).

The adjustment for FY 1999 was 3.68 percent. (63 FR 70777 at 70778, December 22, 1998). This was the greater of the CPI increase for FY 1998 (1.49 percent) or the increase in applicable Federal salaries (3.68 percent).

The adjustment for FY 2000 was 4.94 percent (64 FR 72669 at 72670, December 28, 1999). This was the greater of the CPI increase for FY 1999 (2.62 percent) or the increase in applicable Federal salaries (4.94 percent).

The adjustment for FY 2001 was 3.81 percent (65 FR 79107 at 79108, December 18, 2000). This was the greater of the CPI increase for FY 2000 (2.62 percent) or the increase in applicable Federal salaries (3.81 percent).

The adjustment for FY 2002 is 4.77 percent. This is the greater of the CPI increase for FY 2001 (2.65 percent) or the increase in applicable Federal salaries (4.77 percent).

Compounding these amounts (1.0245 times 1.0368 times 1.0494 times 1.0381 times 1.0477) yields a total compounded inflation increase of 21.23 percent for FY 2002. The adjusted application fee rates are computed by adding one to the decimal equivalent of this percent (0.2123) and multiplying this amount (1.2123) by the FY 2002 statutory application fee rates stated above ($258,451 for applications requiring clinical data, and $129,226 for applications not requiring clinical data or supplements requiring clinical data). For FY 2002 the adjusted application fee rates are $313,320 for applications requiring clinical data, and $156,660 for applications not requiring clinical data or supplements requiring clinical data. These amounts must be submitted with all applications during FY 2002.

B. Estimate of Total Application Fee Revenue

Total application fee revenues for FY 2002 will be estimated by multiplying the number of fee-paying applications FDA expects to receive in FY 2002 (from October 1, 2001, through September 30,

2002) by the fee rates calculated in the preceding paragraph. Before fees can be set for establishment and product fee categories, each of which are projected to be equal to total revenues FDA collects from application fees, FDA must first estimate its total FY 2002 application fee revenues. To do this FDA first determines its FY 2001 fee-paying full application equivalents, and uses that number in a linear regression analysis to predict the number of fee-paying full application equivalents expected in FY 2002. This is the same technique applied in each of the previous 3 fiscal years.

In FY 2001, FDA received and filed 95 human drug applications that require clinical data for approval, 16 that did not require clinical data for approval, and 126 supplements to human drug applications that required clinical data for approval. Because applications that do not require clinical data and supplements that require clinical data are assessed only one-half the full fee, the equivalent number of these applications subject to the full fee is determined by summing these categories and dividing by 2. This amount is then added to the number of applications that require clinical data to arrive at the equivalent number of applications that may be subject to full application fees.

In addition, as of September 30, 2000, FDA refused to file, or firms withdrew before filing, 2 applications that required clinical data, and 5 applications that either did not require clinical data or that were supplements requiring clinical data. The full applications refused for filing or withdrawn before filing pay one-fourth the full application fee and are counted as one-fourth of an application; the applications that do not require clinical data and the supplements refused for filing or withdrawn before filing pay one-eighth of the full application fee and are each counted as one-eighth of an application.

Using this methodology, the number of full application equivalent (FAE) submissions that were received for review in FY 2001 was 167.125, before any exemptions, waivers or reductions. Under PDUFA II, FDA waives application fees for certain small businesses submitting their first application and for certain orphan products. Certain application supplements for pediatric indications are also exempt from fees. In addition, PDUFA II provides a number of other grounds for waivers (public health necessity, preventing significant barriers to innovation, and fees exceed the cost). In FY 2001 waivers or exemptions were applied to 59 FAE submissions (14.5 for orphan products, 12 for small businesses, 19 for pediatric supplements, and 13.5 miscellaneous exemptions/waivers). Therefore, for FY 2001, FDA estimates that it received 108.125 (167.125 minus 59) FAE submissions that will pay fees, after allowing for exemptions, waivers and reductions.

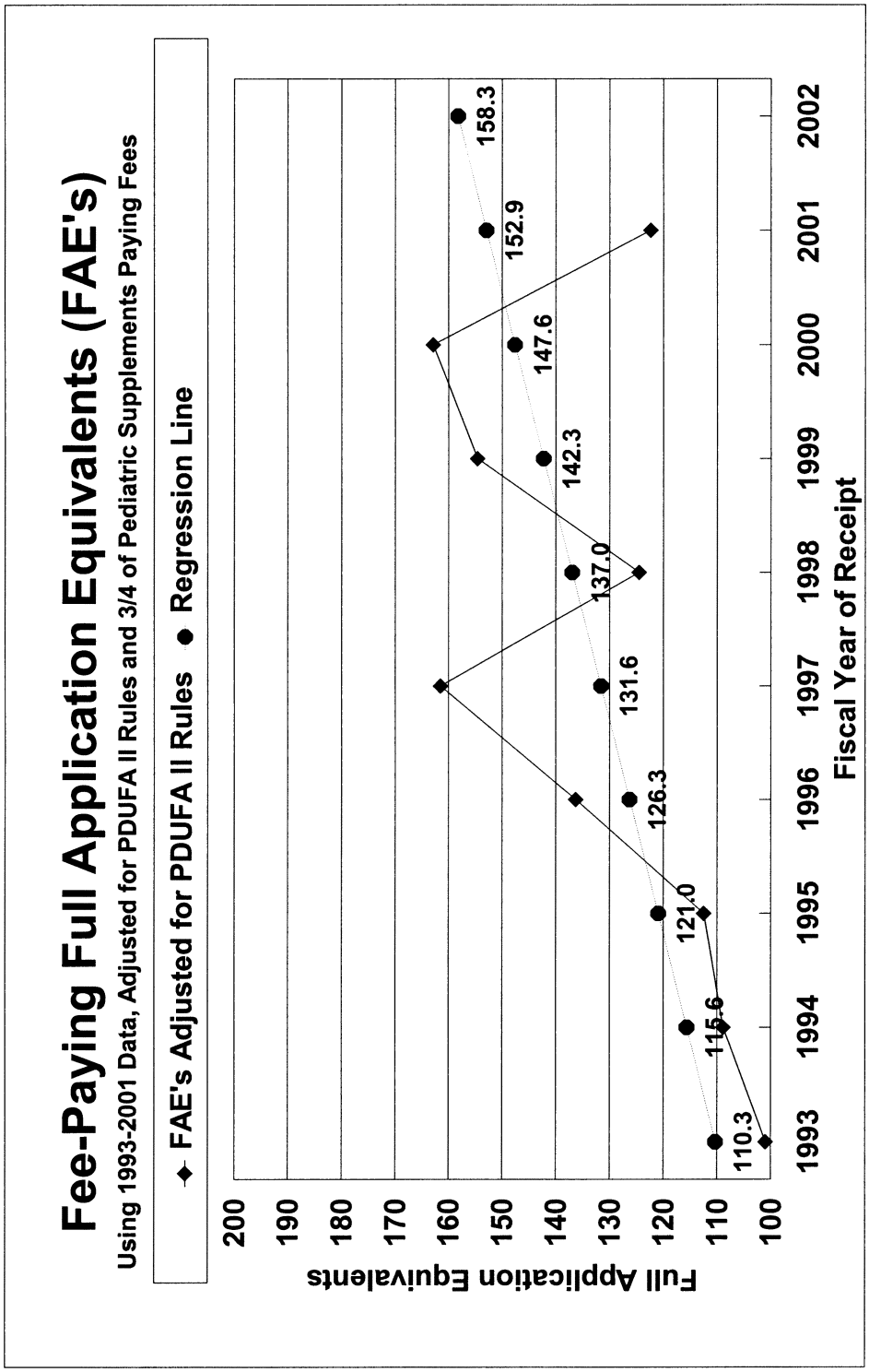
Next a linear regression line based on the adjusted number of fee-paying FAE submissions since 1993, and including our FY 2001 total of FAEs, must be drawn to project the number of FAEs in FY 2002.

In FY 2002, however, additional applications will have to pay fees. All pediatric supplements will be required to pay fees effective January 4, 2002 (for three-fourths of FY 2002). This is the result of section 5 of the Best Pharmaceuticals for Children Act. It repealed the fee exemption for pediatric supplements effective January 4, 2002. Thus, the regression line projecting FY 2002 fee-paying receipts must be drawn to reflect this change. In FY 1998, 8 full fees were exempted for pediatric supplements; the numbers for FY 1999, FY 2000, and FY 2001 respectively were 5.25, 12.5, and 19. Since fees on these supplements will only be paid for three-fourths of FY 2002 (January 1 through September 30, 2002), three-fourths of the number of pediatric supplements waived each year from FY 1998 through FY 2001 (the only years when fees were waived) will be added to the total of fee-paying FAEs received each year.

A linear regression line based on this adjusted number of fee-paying FAE submissions since 1993, and including our adjusted FY 2001 total of 122.375 FAEs (108.125 fee-paying FAEs and three-fourths of the 19 pediatric supplements that were exempted in FY 2001), projects the receipt of 158.3 fee-paying FAEs in FY 2002, as reflected in table 1 of this document and the graph below.

TABLE 1.

Fiscal Year	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Fee-paying FAEs	101.0	108.9	112.5	136.3	161.5	124.5	154.6	162.9	122.4	
Regression Line	110.3	115.6	121.0	126.3	131.6	137.0	142.3	147.6	152.9	158.3



The total FY 2002 application fee revenue is estimated by multiplying the adjusted application fee rate ($313,320) by the number of applications projected to qualify for fees in FY 2002 (158.3), for a total estimated application fee revenue in FY 2001 of $49,598,556. This is the amount of revenue that FDA is also expected to derive both from establishment fees and from product fees.

IV. Adjustment for Excess Collections in Previous Years

Under the provisions of PDUFA II, if the agency collects more fees than were provided for in appropriations in any year after 1997, FDA is required to reduce its anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379h(g)(4)).

In FY 1998, Congress appropriated a total of $117,122,000 to FDA in PDUFA II fee revenue. To date, collections for FY 1998 total $117,737,470---a total of $615,470 in excess of the appropriation limit. This is the only fiscal year since 1997 in which FDA has collected more

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.