administers a national quarantine program to protect the U.S. against the introduction of diseases from foreign countries and the transmission of communicable disease between states; (10) facilitates appropriate cross-cutting collaboration with other NCs, CCID, other CDC programs, and external partners to promote effective surveillance for infectious threats to health; (11) designs and conducts epidemiologic studies to investigate the causes and risk factors for infectious diseases; (12) identifies, evaluates, and promotes the nationwide implementation of interventions designed to prevent infectious diseases, antimicrobial resistance, related adverse events, and medical errors among patients and healthcare personnel; (13) investigates and responds to outbreaks, emerging infections, and related adverse events among patients, healthcare providers, and others associated with the healthcare environment; (14) leads the improvement of domestic and international laboratory practices in clinical and public health laboratories through a quality systems approach; (15) provides services and expertise in development of quality systems to support compliance with FDA regulations on production, distribution, and use of laboratory diagnostic reagents; (16) provides support to CDC laboratories and investigators including provisions of animals, services, materials, and specialized expertise; and (17) provides emergency response coordination to CCID resources and enhanced epidemiologic, surveillance, and laboratory response capacity for bioterrorism and other infectious disease public health emergencies.

Office of the Director (CVK1). (1) Directs and manages the science, programs and activities of the NCPDCID; (2) provides leadership and coordination for the development and implementation of programs to enhance the prevention and control of infectious diseases nationally and internationally; (3) provides leadership and guidance on policy, program planning and development, program integration, management, and operations; (4) identifies and coordinates synergies between national centers and relevant partners; (5) provides technical information services to facilitate dissemination of relevant public health information; (6) provides liaison with other Governmental agencies and international organizations; (7) coordinates, in collaboration with the appropriate CCD and CDC components, international health activities relating to the prevention and control of infectious diseases; (8) advises the Director CCID and the Director, CDC, on policy matters concerning NCPDCID programs and activities; (9) coordinates development and review or regulatory documents and congressional reports; and (10) analyzes health programs and proposed legislation with respect to NCPDCID programs, goals and objectives.

Dated: April 10, 2007.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 07–1905 Filed 4–17–07; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0068]

Medical Device User Fee and Modernization Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss our proposed recommendations for the reauthorization of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA I) for fiscal years (FY) 2008 through 2012, as well as other proposals to improve the review of medical devices and the third party inspection program. These proposed recommendations were developed after discussions with the regulated industry. Section 105 of MDUFMA I directs FDA to publish these proposed recommendations in the **Federal Register**, hold a meeting at which the public may present its views on the recommendations, and provide for a period of 30 days for the public to provide written comments on the recommendations. The public meeting and comment period will provide an opportunity for public input on the proposed recommendations from all interested parties, including the regulated industry, scientific and academic experts, healthcare professionals, and representatives of patient and consumer advocacy groups.

DATES: The public meeting will be held on April 30, 2007, from 12 noon to 5 p.m. Registration to attend and to present at the meeting must be received by April 25, 2007. (See section III.B of this document for details on registration.) Submit written comments by May 18, 2007. Transcripts will be available approximately 30 days after the meeting. (See section III.C of this document for more details on transcript availability.)

ADDRESSES: The public meeting will be held at the Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For information regarding this notice, contact*: Erik Mettler, Office of Policy and Planning, Food and Drug Administration (HF–11), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *Erik.Mettler@fda.hhs.gov*.

For information regarding registration, contact: Cynthia Garris, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration (HFZ–220), 1350 Piccard Ave., Rockville, MD 20850, phone: 240–276–3150 ext. 121, FAX: 240–276–3151; e-mail: *cynthia.garris@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

MDUFMA I (Public Law 107–250, October 26, 2002) amended the Federal Food, Drug, and Cosmetic Act (the act) to provide FDA with the following new responsibilities and resources:

- User fees for premarket reviews of certain device premarket applications (see sections 737 and 738 of the act (21 U.S.C. 379i and 379j));
- Performance goals to improve medical device reviews (see section 101(3) of MDUFMA I and section 738(g)(1) of the act);
- Establishment inspections to be conducted by accredited third-parties when certain conditions are met (see section 704(g) of the act (21 U.S.C. 374)); and
- Improved oversight and coordination of reviews of combination products (products that combine devices, drugs, or biologics) (see section 503(g) of the act (21 U.S.C. 353(g))).

A. Medical Device User Fees and Performance Goals

In the years prior to MDUFMA I, FDA's resources for our device and radiological health programs had increased at a lower rate than FDA's

costs. As stated in the House Report to H.R. 3580:

The medical device industry is growing rapidly. The complexity of medical device technology is increasing at an equally rapid pace. Unfortunately, FDA's device review program lacks the resources to keep up with the rapidly growing industry and changing technology. Because prompt approval and clearance of safe and effective medical devices is critical to improving public health, it is the sense of the Committee that adequate funding for the program is essential. (U.S. Congress, House Committee on Energy and Commerce, Medical Device User Fee and Modernization Act of 2002, report to accompany H.R. 3580, 107th Cong., 2nd sess., part 1 (Washington: GPO, 2002), pp. 23.)

Section 102 of the House Report recognized the importance of user fees in improving the device review program:

This title gives FDA the authority to collect user fees from manufacturers seeking to market medical devices. In this new program, manufacturers pay fees to FDA in exchange for FDA's agreement to endeavor to meet device review performance goals that will significantly improve the timeliness, quality, and predictability of the agency's review of devices. (Id. at 23–24.)

Under MDUFMA I, the industry provides funds through user fees that are available to FDA, in addition to appropriated funds, to spend on the device review process. Our authority to collect and spend user fees is ''triggered'' only in years when a base amount of appropriated funds, adjusted for inflation, is appropriated and spent on the process for the review of device applications.

In return for the additional resources provided by medical device user fees, FDA is expected to meet performance goals defined in a November 14, 2002, letter from the Secretary of the Department of Health and Human Services to the Chairman and Ranking Minority Members of the Committee on Health, Education, Labor and Pensions Committee of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representatives. This letter is generally referred to as the ''FDA Commitment Letter.'' See 148 Cong. Rec. S11549–01 (2002). A few goals applied during FY 2003 and FY 2004, allowing FDA time to hire staff, build infrastructure, provide guidance to industry, and take other actions to implement the new law. More goals went into effect each year from FY 2005 through FY 2007, and the goals become more ambitious each year. These goals include ''FDA decision'' goals, under which FDA makes a specific decision within a specified time (and similar goals for FDA to ''review and act on'' certain biologics applications within a specified time), and cycle goals, which refer to FDA actions prior to a final action on a submission. These goals apply to the review of device premarket approvals (PMAs), panel-track supplements, premarket reports, expedited PMAs, 180-day PMA supplements, and 510(k)s in FDA's Center for Devices and Radiological Health (CDRH) and FDA's Center for Biologics Evaluation and Research (CBER), and to Biologics License Applications (BLAs), BLA supplements, and BLA resubmissions, and BLA supplement resubmissions in CBER. Phased in over the 5 years of MDUFMA I, the final goals for FY 2007 included an FDA decision on:

- 90 percent of PMAs, panel-track supplements, and premarket reports within 320 days;
- 50 percent of PMAs, panel-track supplements, and premarket reports within 180 days;
- 90 percent of expedited PMAs within 300 days;
- 90 percent of 180-day PMA supplements within 180 days;
- 80 percent of 510(k)s within 90 days;
- 90 percent of standard BLAs within 10 months;
- 90 percent of priority BLAs within 6 months;
- 90 percent of standard BLA efficacy supplements in 10 months;
- 90 percent of priority BLA efficacy supplements within 6 months;
- 90 percent of ''Class 1'' BLA resubmissions and BLA supplement resubmissions within 2 months;
- 90 percent of ''Class 2'' BLA resubmissions and BLA supplement resubmissions within 6 months; and
- 90 percent of BLA manufacturing supplements requiring prior approval within 4 months.

The goals also included interim cycle goals that were phased in over time. FDA is on track to meet or exceed nearly all of these performance goals. These performance goals, as outlined in the FDA Commitment Letter, will no longer be in effect after MDUFMA I sunsets on October 1, 2007. See section 107 of MDUFMA I.

B. Other Topics in MDUFMA I

In addition to its provisions relating to medical device user fees and performance goals, MDUFMA I contained other provisions. These provisions include:

- Authorization for a program that allows establishment inspections to be conducted by third party accredited persons (APs), under carefully prescribed conditions;
- Establishment of a new office in the Office of the Commissioner to coordinate the review of combination products;
- Authorization to require electronic registration of device establishments, once FDA finds that electronic registration is feasible; and
- Explicit authorization for the ''modular'' review of PMAs.

The user fees provided by MDUFMA I, and the additional appropriations anticipated by the new law, have allowed us to make improvements in the device review program. FDA's progress towards meeting MDUFMA I's performance goals has been accomplished through:

- Targeted hiring, including medical specialists, statisticians, software experts, and engineers;
- Increased use of outside experts, particularly for novel technologies;
- Improvements to FDA's information technology systems, such as enhanced tracking of applications and reporting systems; and
- Additional guidance documents that assist industry in preparing their applications to better address regulatory issues, such as how to qualify for small business fee waivers and discounts, how to prepare a ''modular'' premarket approval application, and how to obtain expedited review of a premarket submission.

These actions have led to improved FDA review times and greater predictability in the device review process.

In addition, we have made significant progress towards meeting other fundamental objectives of MDUFMA I. For example, FDA established an Office of Combination Products that is improving coordination of combination product reviews. Combination products are products comprised of different types of regulated articles (i.e., drug-device, drug-biologic, and device-biologic products). Although primary responsibility for the oversight of these products remains with the product Centers, the Office of Combination Products assigns combination products to the product Centers, ensures the timely and effective premarket review of combination products, and ensures the consistency and appropriateness of postmarket regulation of combination products. FDA also met the statutory requirement to establish a third-party inspection program. This option may be particularly useful to U.S. firms who

compete in international markets and are faced with multiple sets of regulatory requirements, as a single inspection may satisfy both U.S. and foreign requirements, and might also meet International Organization for Standardization (ISO) or other international standards requirements.

In August 2005, Congress passed the Medical Device User Fee Stabilization Act (Public Law 109–43, August 1, 2005) (MDUFSA), which modified several provisions of MDUFMA I.

MDUFSA:

- Repealed the FY 2003 and FY 2004 appropriations trigger requirements;
- Modified the FY 2005 through FY 2007 minimum appropriation requirements for the device and radiological health line of FDA's appropriation to be within 1 percent below the calculated appropriations trigger;
- Fixed annual fees for FY 2006 and FY 2007 at an amount providing an 8.5 percent rate of increase each year;
- Expanded the definition of ''small business'' for FY 2006 and FY 2007, making more firms eligible for reduced small business fees; and
- Repealed the ''compensating adjustment'' that allowed FDA to adjust user fee rates to make up for revenue lost when user fee revenues did not meet projections in a prior year.

The user fee provisions of MDUFMA I will sunset on October 1, 2007 if not reauthorized. In preparing our proposed recommendations for reauthorization, we have conducted technical discussions with the regulated industry and have consulted with stakeholders each year at a public meeting as required by law.

Congress directed FDA to publish in the **Federal Register** the proposed recommendations developed through this process after negotiations with the regulated industry, present the proposed recommendations to the congressional committees specified in the statute, hold a public meeting at which the public can present its views on the proposed recommendations, and provide for a period of 30 days for the public to provide written comments on the proposed recommendations. See section 109 of MDUFMA I.

The purpose of this notice is to publish the recommendations we propose to offer Congress and announce the dates for the upcoming public meeting and written comment period. After the public meeting and the close of the 30-day comment period, we will undertake a careful review of all the public comments we receive on these proposed recommendations.

II. What We Are Proposing to Recommend to Congress?

Our goal for the legislative package to reauthorize medical device user fees and to make other improvements (MDUFMA II) is to build upon the performance goals we are pursuing for FY 2007 while providing predictable user fees for industry and financial stability and predictability in funding for FDA over the next 5 years. Our proposed recommendations fall into the following two major categories: (1) Proposals to ensure sound financial footing for the medical device review program and (2) proposals to enhance the process for premarket review of device applications.

A. Proposed Recommendations to Ensure Sound Financial Footing

Although user fees have provided substantial resources to FDA since the beginning of the program, total resources for medical device review, including funds from both appropriations and user fees, have not kept up with our increasing costs. FDA has experienced an increase in our costs of pay and benefits per ''full time equivalent'' (FTE) averaging 5.8 percent per year over the most recent 5 years. Nonsalary costs, including the costs of rent and contract support, have also increased at the same rate per FTE. We are proposing changes to the financial provisions of MDUFMA I to place FDA on more sound financial footing so we can continue with the program and make enhancements to it.

1. Adjustment of Total Revenue for Device Review to Ensure a 6.4 Percent Increase From Year to Year Over the Next 5 Years

Detailed analysis of FDA's recent costs history and anticipated increased costs over the next 5 years anticipate annual increases at 6.4 percent each year. Increases of 6.4 percent per year are necessary for FDA to be able to maintain the current level of staff to support the medical device review process. The primary drivers of this rate of increase are rent, security, and statutorily mandated payroll and benefits increases. In developing cost estimates for MDUFMA II, we used our FY 2005 spending on the device review process (including fees and appropriations) and estimated that the costs for the program would increase at 6.4 percent each year. Table 1 of this document represents FDA's estimate of the total resources it will need for device review from appropriations and user fees combined over the 5-year period 2008 through 2012.

TABLE 1.—TOTAL RESOURCES NEEDED FOR THE DEVICE REVIEW PROCESS ($ MILLIONS)

Fiscal Year	2008	2009	2010	2011	2012	5-Year Total
Dollars (millions)	$220	$234	$249	$265	$281	$1,249

The annual fee increases assumed will ensure a stable program that will not increase over the 5 years of MDUFMA II, but that should remain stable in its capabilities and personnel strength. The proposed fee structure would have application fees lower than those paid in 2007 in almost all application categories over the 5 years of MDUFMA II, but would add new annual establishment and annual report fees and some new application fees (discussed more below). Total fee revenues in FY 2008 would increase by approximately 31 percent over estimated FY 2007 fee revenues, and by 8.5 percent per year each subsequent year through FY 2012, as shown in table 2 below.

TABLE 2.—TOTAL ESTIMATED FEE REVENUES ($ MILLIONS)

Fiscal Year	2008	2009	2010	2011	2012	5-Year Total
Total	$48.5	$52.5	$57.0	$61.9	$67.1	$287.0

2. More Stable Fee Structure

All fee revenues in MDUFMA I were derived from application fees only, which fluctuated significantly from year to year. Under MDUFMA I, fee revenues repeatedly fell short of expectations. FDA is proposing to recommend two new fees in MDUFMA II that would generate about 50 percent of the total fee revenue and that would be more stable than application fees. The new fees are: (1) An annual establishment registration fee and (2) an annual fee for filing periodic reports. This would allow for significant reduction in MDUFMA II of existing application fees.

The establishment fee would be paid once each year by each device manufacturer (including an establishment that sterilizes or otherwise makes a device for a specification developer or any other person), single-use reprocessor, and specification developer. It is proposed to start at $1,706 in 2008 and would generate about $21.8 million (45 percent of total fee revenues), assuming that 12,750 establishments pay this fee. (The proposal would allow an increase in FY 2010 over the annual rate of increase if fewer than 12,250 establishments pay the fee in FY 2009 to ensure that the fees collected from this source total 45 percent of fee revenues. This increase would not be more than 8.5 percent above the annual rate of increase.) A firm would not be considered to be legally registered each year without the payment of this fee, which is to be completed electronically.

The annual fee for filing periodic reports is proposed to start at $6,475 in FY 2008 and would generate about $2.5 million in FY 2008, or about 5 percent of fee revenues assuming that we receive reports on 425 devices subject to periodic reporting and 10 percent pay the reduced small business fee of $ 1,619.

The remaining 50 percent of revenues would come from application fees. All proposed application fees would be significantly lower than they were in FY 2007. The proposed fee for a PMA or BLA would be set at $185,000 in FY 2008—34 percent less than the $281,600 charged in FY 2007. The proposed fee for a panel-track supplement would be charged at 75 percent of the rate for a PMA, rather than at 100 percent of that rate as was the case in FY 2003 through FY 2007, so the proposed panel-track supplement fee in FY 2008 of $138,750 would be 51 percent less than the FY 2007 fee of $281,600. The fee for a 180-day PMA supplement is proposed at 15 percent of the PMA fee, rather than at 21.5 percent of that rate as was the case in FY 2003 through FY 2007, so the proposed 180-day PMA supplement fee in FY 2008 of $27,750 would be 54 percent less than the FY 2007 fee of $60,544. The fee for a real-time supplement is proposed at 7 percent of the PMA fee, rather than at 7.2 percent of that rate as was the case in FY 2003 through FY 2007, so the proposed real-time supplement fee in FY 2008 of $12,950 would be 36 percent less than the FY 2007 fee of $20,275. The fee for a 510(k) is proposed at 1.84 percent of the PMA fee, rather than at 1.42 percent of that rate as was the case in FY 2003 through FY 2007, so the proposed 510(k) fee in FY 2008 of $3,404 would be 18 percent less than the FY 2007 fee of $4,158.

FDA is proposing two new fees for applications not currently subject to fees. They are: (1) A fee for 30-day notices (making modifications to manufacturing procedures or methods) that would be 1.6 percent of the fee for a full PMA (for a 30-day notice fee of $2,960 in FY 2008) and (2) a fee for a request for classification information under section 513(g) that would be assessed at 1.35 percent of the cost of a full PMA (for a 513(g) fee of $2,498 in FY 2008). Both of these applications require significant work by FDA, and the proposed fees reflect the work that they involve, on average.

Each of the proposed fees would increase each year by 8.5 percent to ensure that fee revenues contribute their expected share to total program costs, and to provide industry with stability and predictability in the fee revenues it would expect to pay.

3. Changes in the Fee Structure for Small Businesses

In an effort to reduce the burden on small businesses, FDA is proposing to reduce the rates paid by firms meeting the definition of a small business under MDUFMA. The criteria for meeting the small business definition is not proposed to change, other than as discussed below for entities that do not file returns with the U.S. Internal Revenue Service, but the proposed fee rates for qualifying small businesses would be lower. We are proposing to reduce the rates for small businesses for premarket applications, panel-track PMA applications, BLA efficacy supplements, 180-day PMA supplements, real-time PMA supplements, and annual reports, from 38 percent to 25 percent of the standard fee for the particular type of submission. We are also proposing to reduce the rates for small businesses for 30-day notices, 510(k) premarket notification submissions, and 513(g) requests for classification information from 80 percent to 50 percent of the standard fee for the particular type of submission. These are significant reductions that should provide substantial relief to qualifying small businesses.

The following table summarizes the reductions in fees for qualifying small businesses proposed for FY 2008.

TABLE 3.—MEDICAL DEVICE USER FEES PROPOSED FOR FY 2008

Type of Fee	Standard Fee	Small Business Fee
Premarket application (PMA, BLA, premarket report, product development protocol)	$185,000	$46,250
Panel-track PMA supplement	$138,750	$34,688
180-day PMA supplement	$27,750	$6,938
BLA efficacy supplement	$185,000	$46,250
Real-time PMA supplement	$12,950	$3,237
30-day notice	$2,960	$1,480
510(k) premarket notification submission	$3,404	$1,702
Request for classification information	$2,498	$1,249

In addition, FDA is proposing that the small business provisions be expanded to allow a way for firms that do not file tax returns with the U. S. Internal Revenue Service to also qualify for small business rates, based on certifications from the national taxing authorities where the firm and each of its affiliates file their taxes, and signed affidavits from the head of the firm or its chief financial officer and from each of its affiliates.

4. Technical Changes to Increase Administrative Efficiency of the User Fee Program

We are proposing a change to the current offset provision of MDUFMA I. The current provision requires us to reduce fees in a subsequent year if collections in any year exceed the amount appropriated, but does not have a parallel provision to increase fees in a subsequent year if collections fall short of amounts appropriated from fees. The modification we are recommending to propose would allow us to aggregate all fees collected over the first four years of MDUFMA II, from FY2008 through FY 2011 and compare that amount to the aggregate amount appropriated for the same period. A reduction would be made in fees in the final year only if the amount collected in the 4-year period exceeds the amount appropriated for the same period. We believe this aggregation over 4 years provides for greater financial stability for FDA than treating each year in isolation.

5. Electronic Registration

FDA is proposing to change section 510(p) of the act (21 U.S.C. 360(p)) to facilitate the submission of registration and listing information by electronic means, except in those rare situations where FDA agrees that electronic submission is not feasible, in order to collect establishment registration fees for FY 2008. The modification would require electronic submission of registration and listing information without going through the rulemaking process to ensure timely collection of establishment registration fees for FY 2008. We believe electronic registration is essential for efficient implementation of any proposal for an establishment registration fee.

6. Triggers

MDUFMA I has three triggers. One tied to appropriations for the device line and two tied to agency spending on device review and inspections. We are proposing to extend the current triggers through MDUFMA II.

B. Enhancing the Process for Premarket Review

In the area of premarket review, FDA is proposing to recommend enhancements in the following eight areas: (1) Performance goals; (2) interactive review; (3) guidance document development; (4) diagnostic imaging products; (5) in vitro diagnostics; (6) meetings; (7) quarterly performance reports; and (8) reviewer training.

1. Performance Goals

FDA is proposing to meet more rigorous goals for MDUFMA II that build on the progress made in MDUFMA I. In making these proposals, we have taken into account the efficiencies accomplished in MDUFMA I and planned for in MDUFMA II. These efficiencies include additional scientific, regulatory, and leadership training; additional staff, including those with expertise demanded by increasingly complex device reviews; expanded use of outside experts; and information technology improvements that allow us to better track and manage the device review process.

In MDUFMA II, we are proposing to eliminate the cycle goals that we believe are an impediment to reaching the ultimate objective of MDUFMA—to get safe and effective devices to patients and healthcare professionals more quickly. In order to meet the performance goals in the FDA Commitment Letter, we put business processes in place to meet the goals for final decisions, as well as for interim cycle goals. However, FDA believes that an unintended consequence of the cycle goals is that, because we must determine whether or not to send a major deficiency letter, ''not approvable'' letter, or other interim action earlier in the review process, we are less likely to have sufficient time to engage in informal interactions with the applicant to resolve outstanding questions before making that determination. Consequently, we are more likely to issue a negative interim decision. We are proposing to eliminate these cycle goals and only have performance goals for final decisions.

In MDUFMA II, we are proposing to improve our performance in reaching a final decision for the following applications:

- A decision for 60 percent of nonexpedited PMAs and panel-track PMA supplements within 180 days and for 90 percent within 295 days;
- A decision for 50 percent of expedited PMAs and expedited panel-track PMA supplements within 180 days and for 90 percent within 280 days;
- A decision for 90 percent of 510(k)s within 90 days and for 98 percent within 150 days;
- A decision for 85 percent of 180-day PMA supplements within 180 days and for 95 percent within 210 days;[1] and
- A decision for 80 percent of real-time PMA supplements within 60 days and for 90 percent within 90 days.

We are also adding a goal for PMA modules in MDUFMA II. We are proposing to take action on 75 percent of PMA modules within 90 days, and for 90 percent within 120 days.

Where specific quantitative goals have not been established, we are proposing that we would, at a minimum, maintain current performance in review areas, such as for investigational device exemptions (IDEs) and 30-day notices.

2. Interactive Review

Under the proposed recommendations, we would continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and sponsors to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and sponsors. Interactive review is intended to: (a) Prevent unnecessary delays in the completion of the review; (b) avoid surprises to the sponsor at the end of the review process; (c) minimize the number of review cycles and the extent of review questions conveyed through formal requests for additional information; and (d) ensure timely responses from sponsors. We believe that all forms of communication should be used as tools to facilitate interactive review, including, but not limited to, the following: (a) E-mail; (b) one-on-one telephone calls; (c) telephone conferences; (d) videoconferencing; (e) fax; and (f) face-to-face meetings.

3. Guidance Document Development

Under the proposed recommendations, we would continue to develop guidance documents to the extent possible without adversely impacting the review timeliness for MDUFMA-related submissions. In addition, FDA would post a list of guidance documents it is considering for development and provide stakeholders an opportunity to provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

[1] Under MDUFMA I, FDA issues a ''not approvable'' letter to indicate deficiencies in an application and to request additional information, which counts as an action that meets the goals for 180-day PMA supplements. Under MDUFMA II, the reviewer in the same situation will be able to issue a ''major deficiency'' letter, which will not count towards meeting the 180-day PMA supplement goals. The MDUFMA II goal will be more ambitious in practice because it reflects a more meaningful decision, reached after FDA has worked with the sponsor to discuss deficiencies and to obtain additional information.

4. Diagnostic Imaging Products

Diagnostic imaging devices that are sometimes used concurrently with diagnostic drug and biological products (such as contrast agents and radiopharmaceuticals)—so-called ''concomitant use products''—present important questions of efficient regulation and consultation between product Centers that are similar to those raised by combination products.

In response to these concerns, FDA would develop a guidance document, after consultation with affected parties, intended to ensure timely and effective review of, and consistent and appropriate postmarket regulation and product labeling requirements for, diagnostic imaging devices used with approved imaging contrast agents and/or radiopharmaceuticals. We propose to publish draft guidance by the end of FY 2008 and allow for a 90-day public comment period. We propose to issue a final guidance within one year of the close of the comment period.

5. In Vitro Diagnostics (IVDs)

To facilitate the development of IVD devices, FDA would continue to explore ways to clarify regulatory requirements and to reduce regulatory burden, as appropriate. FDA proposes to:

- Draft or revise guidance on the conduct of clinical trials involving de-identified leftover specimens, clinical trial design issues for molecular diagnostic tests, migration studies, herpes simplex virus, enterovirus, and influenza testing;
- Conduct a pilot program to evaluate integrating the 510(k) review and Clinical Laboratory Improvement Amendments (CLIA) waiver review processes for possible increased efficiencies. This pilot would include only voluntary participants from industry, and the applications involved in the pilot would not be counted toward the MDUFMA II performance goals.
- Consider industry proposals on acceptable CLIA waiver study protocols, develop acceptable protocol designs, and make them available by adding appendices to the guidance or by posting redacted protocols on the OIVD Web site.
- Track and report our performance on CLIA waiver applications and share this information with industry annually and then evaluate, at the end of year two, whether user fees and performance goals for CLIA waivers should be considered for MDUFMA III;
- Review a list of class I and II low risk IVD devices, provided by industry, to determine whether any of them could be exempted from premarket notification and allow interested parties to petition for exemptions consistent with 510(m)(2);
- Conduct a review of the pre-IDE program to address issues raised by industry.

6. Meetings

FDA would make every effort to schedule informal and formal meetings, both before and during the review process, in a timely way, and industry would make every effort to provide timely and relevant information to make the meetings as productive as possible. These meetings include, but are not limited to the following: pre-submission meetings, determination meetings, agreement meetings, and 100-day meetings.

7. Quarterly Performance Reports

FDA would report quarterly its progress toward meeting the quantitative goals described in this letter. In addition, for all submission types, we would track total time (time with FDA plus time with the company) from receipt or filing to final decision (approval, denial, substantial equivalence (SE), or nonsubstantial equivalence (NSE)). We would also provide, on an annual basis, de-identified review performance data for the branch with the shortest average review times and the branch with the longest average review times for 510(k)s, 180-day supplements, and real-time supplements.

8. Reviewer Training

As resources permit, FDA would apply user fee revenues to support reviewer training that is related to the process for the review of devices, including training to enhance scientific expertise. We would provide summary information on the types of training provided to staff on an annual basis.

C. Third Party Inspection Program

FDA is proposing to recommend changes to the third party accredited person (AP) inspection program in three major areas. APs are firms trained and accredited by FDA to conduct biennial inspections of certain medical device firms for compliance with good manufacturing practices. The proposals are intended to increase the quantity of useful information FDA has about the compliance status of medical devices marketed in the United States and to permit FDA to focus its inspectional resources on those firms and products posing the greatest risk to public health.

First, FDA is proposing to streamline the administrative burdens associated with qualifying for the program. For example, rather than having to petition FDA for clearance to use an AP, the proposal would require only that firms provide FDA with 30 days prior notice of their intent to use an AP listed on FDA's Web site.

Second, we are proposing to expand participation in the program. For example, the current AP program restricts qualified manufacturers of class II and class III medical devices to two consecutive AP inspections after which FDA must conduct the next inspection, unless the manufacturer petitions and receives a waiver from us. We are proposing to permit firms to use APs for an unlimited number of consecutive inspections without seeking a waiver. However, we would continue to conduct ''for cause'' or follow-up inspections whenever we deem such inspections appropriate.

Third, we are proposing to permit device companies to voluntarily submit to FDA reports by third parties assessing conformance with an appropriate international quality systems standard, such as those set by the International Standards Organization. We would consider the information in these reports in setting our inspectional priorities.

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will We Use?

Through this notice, we are announcing the convening of a public meeting to hear stakeholder views on the recommendations we propose to provide to Congress on the reauthorization of MDUFMA II.

We will conduct the meeting on April 30, 2007. (see **ADDRESSES**). In general, the meeting format will include brief presentations by FDA, but will focus on hearing from different stakeholder interest groups (such as patient advocates, consumer advocates, industry, health professionals, and academic researchers). We will also give individuals the opportunity to make presentations at the meeting, and for organizations and individuals to submit written comments to the docket after the meeting.

B. How Do You Register for the Meeting or Submit Comments?

If you wish to attend and/or make a presentation at the meeting, send an e-mail message to Erik Mettler or Cynthia Garris (see **FOR FURTHER INFORMATION CONTACT**) by April 25, 2007. Your e-mail should include the following information: Name, company, company

address, company phone number, and e-mail address. You will receive a confirmation within 2 business days.

We also will accept walk-in registration at the meeting site, but space is limited, and we will close registration when maximum seating capacity (approximately 100) is reached.

We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

Additionally, regardless of whether you wish to make a presentation or simply attend the meeting, please notify us if you need any special accommodations (such as wheelchair access or a sign language interpreter).

If you would like to submit comments regarding these proposed recommendations, please send your comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Submit your comments no later than May 18, 2007.

C. Will Meeting Transcripts Be Available?

We will prepare a meeting transcript and make it available on our Web site (*http://www.fda.gov*) after the meeting. We anticipate that transcripts will be available approximately 30 working days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, between 9 a.m. and 4 p.m. Monday through Friday.

Dated: April 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–1919 Filed 4–16–07; 1:52 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–07–4301]

Memorandum of Understanding Between the National Cancer Institute and the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) of the Department of Health and Human Services (DHHS). The purpose of this MOU is to establish a formal collaboration between FDA and NCI regarding the creation of a common standards-based data repository to facilitate the electronic exchange and analysis of data from research studies on investigational drugs in a fully secure manner.

DATES: The agreement became effective March 2, 2007.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation Research (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7784 e-mail: *randy.levin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: April 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S