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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1364]

Prescription Drug User Fee Act (PDUFA); Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to hold a public meeting on the Prescription Drug User Fee Act (PDUFA). The legislative authority for PDUFA expires at the end of September 2002, and without further legislation the fees and resources provided under PDUFA will also expire. FDA is now considering what features it should advocate in proposing new or amended authorizing legislation. Section 903(b) of the Federal Food, Drug, and Cosmetic Act encourages FDA to consult with stakeholders, as appropriate, in carrying out agency responsibilities. Accordingly, FDA will convene a public meeting to hear stakeholder views on this subject. FDA is proposing four specific questions, and the agency is interested in responses to these questions and any other pertinent information stakeholders would like to share.

DATES: The public meeting will be held on September 15, 2000, at 9 a.m. Submit written comments by October 31, 2000. Registration to attend the meeting must be received by September 8, 2000.

ADDRESSES: The meeting will be held in the Auditorium, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC (between 3d and C St.).

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: FDADockets@oc.fda.gov, or via the FDA website at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. More information about various aspects of PDUFA and this public meeting are available on the Internet at: <http://www.fda.gov/oc/pdufa2/meeting2000.html>.

REGISTRATION AND REQUEST FOR ORAL PRESENTATION: If you wish to make an oral presentation during the open public comment period of the meeting, you must specify on your registration form or with the registration contact person listed below that you wish to make a presentation. You must submit along with your registration form: (1) A brief written statement of the general nature of the views you wish to present, (2) the names and addresses of all persons who will participate in the presentation, and (3) an indication of the approximate time that you request to make your presentation. Depending on the number of people who register to make presentations, FDA may have to limit the time allotted for each presentation.

In order to register, you must submit your name, title, business affiliation, address, telephone, fax number (optional), and email address (optional).

REGISTRATION CONTACT: All registration materials should be sent to Patricia Alexander, Office of Consumer Affairs (HFE-40), Food and Drug Administration, Rockville, MD 20857, 301-827-4391, FAX 301-827-2866, e-mail: palexand@oc.fda.gov, or on the Internet at <http://www.fda.gov/oc/pdufa2/meeting2000.html>.

All registration will be accepted on a first-come, first-served basis. Speakers will be chosen in order of registration. All other comments should be sent to the FDA docket.

If you need special accommodations due to a disability, please inform the contact person when you register.

FOR FURTHER INFORMATION CONTACT: Virginia Cox, Office of the Commissioner (HF-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3409, FAX 301-594-6777, e-mail: vcox@oc.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1992, Congress passed PDUFA. PDUFA authorized FDA to collect fees from companies that produce certain human drug and biological products. The original PDUFA had a 5-year life;

it ended in 1997, the same year Congress passed the FDA Modernization Act (FDAMA). Part of FDAMA included an extension of PDUFA (PDUFA II) for an additional 5 years.

PDUFA's original intent was to provide FDA with additional revenue so it could hire more reviewers and support staff and upgrade its information technology to speed up the application review process for human drug and biological products without compromising review quality. The revenues are provided by a set of three fees, with one-third of the total annual revenue coming from each of the following fees:

1. Application fees for the submission of certain human drug or biological application (in fiscal year (FY) 2000, \$285,740 per application with clinical data, and \$142,870 per application without clinical data or per supplemental application with clinical data);
2. Annual establishment fees paid for each establishment that manufactures prescription drugs or biologicals (in FY 2000, \$141,971 per establishment); and
3. Annual product fees assessed on certain prescription drug and biological products (in FY 2000, \$19,959 per product).

In the aggregate these fees are expected to generate \$135 million this FY, and increase to about \$162 million in FY 2002, the last year of PDUFA II. No separate fees are charged for investigational new drug applications. However, since the review of investigational new drug applications is included in the definition of the process for the review of human drug applications, as defined in PDUFA, FDA uses some of the application, establishment, and product fees collected for the review of investigational new drug applications.

In consultation with industry and the Congress, FDA agreed to meet a set of review performance goals that became more stringent each year if FDA also received sufficient fee resources to enable goal achievement. These goals applied to the review of original new human drug and biological applications, resubmissions of original applications, and supplements to approved applications. FDA met every PDUFA I performance goal and, to date, has met all but one PDUFA II performance goal. Industry also insisted on a statutory provision that fees could

only be collected and spent each year if a large, inflation-adjusted portion of drug review costs would continue to be funded from appropriations rather than fees, so that the fees were funding additional drug review resources rather than replacing appropriations.

Under PDUFA II, the review goals continue to shorten. By 2002, the PDUFA II goals call for FDA to review and act on 90 percent of:

1. Standard new drug and biological product applications and efficacy supplements within 10 months;
2. Priority new drug and biological product applications and efficacy supplements (i.e., for products providing significant therapeutic gains) within 6 months;
3. Manufacturing supplements within 6 months, and those requiring prior approval within 4 months;
4. Class 1 resubmissions within 2 months, and Class 2 resubmissions within 6 months.

In addition, PDUFA II added a new set of procedural goals intended to improve FDA's responsiveness to, and communication with, industry sponsors during the early years of drug development. These goals specify timeframes for activities such as scheduling meetings and responding to various sponsor requests. While PDUFA's original intent was to speed up the review process, PDUFA II's intent is to speed up the entire drug development process.

PDUFA has had a dramatic and undeniable impact on the drug review process. Total resources for drug review activities have increased from \$120 million in 1992, before PDUFA was enacted, to an estimated \$325 million in FY 2002, about half of which will come from fees paid by industry. These resources allowed FDA to increase its drug and biological review staff by almost 60 percent between 1993 and 1997, adding about 660 staff-years to the program by 1997. By the end of PDUFA II in 2002, FDA expects to have added another 313 staff-years of effort to this program. These additional staff, and resources to support them, have enabled FDA to respond more rapidly to new drug and biologic applications without compromising review quality.

While it is important to note that PDUFA's goals specify decision times, not approval times, both decision and approval times have decreased dramatically. Total approval time, the time from

the initial submission of a marketing application to the issuance of an approval letter, has dropped from a pre-PDUFA median of 23 months to 12 months. Total approval time for priority applications, those for products providing significant therapeutic gains, has dropped from a median of over 12 months in the early PDUFA years to 6 months. In addition, because FDA has put greater effort into communicating what it expects applicants to submit, a higher percentage of applications are being approved. Before PDUFA, only about 60 percent of the applications submitted were ultimately approved. Now, about 80 percent are approved. For the consumer, this has meant more products available more quickly.

The agency has also encountered some challenges with PDUFA. Assuring that enough appropriated funds are spent on the process for the review of human drug applications to meet requirements of PDUFA, and at the same time spending our resources in a way that best protects the health and safety of the American people is becoming increasingly difficult. Each year, the amount that FDA must spend from appropriations on the drug review process is increased by an inflation factor. Yet, since 1992 FDA has not received increased appropriations to cover the costs of the across-the-board pay increases that must be given to all employees.

The result is that our workforce and real resources for most programs other than PDUFA have contracted each year since 1992 while we struggle to ensure that enough funds are spent on the drug review process to meet this PDUFA requirement. Several consecutive years of operating in this way have made it difficult to continue to further reduce staffing levels in FDA programs other than drug review. We are increasingly concerned that spending enough appropriations on the drug review process to meet the statutory conditions makes FDA less able to manage the resources available in a way that best protects the public health and merits public confidence. Just one example of an area we have not been able to fund adequately is responding to reports of adverse events related to the use of prescription drugs.

II. Scope of Discussion

The legislative authority for PDUFA II expires at the end of September 2002, and without further legislation the fees and resources they have provided will also expire. FDA is now considering what characteristics and conditions it should advocate in proposing new or amended authorizing legislation. Section 903(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)) encourages FDA to consult with stakeholders, as appropriate, in carrying out agency responsibilities. Accordingly, FDA will convene a public meeting on September 15, 2000. Interested persons are invited to attend and present their views.

A list of questions that we are asking interested parties to address at this meeting follows:

1. Since 1993 FDA has been receiving fees for the review of certain human drug and biological products. As a result, FDA has implemented management improvements that have substantially decreased the time for new drug review and made new medications available to the public faster. Do you view this as a benefit of the user fee program that should be maintained in the future? What are some of the other benefits that you think are important? How do you think the program can be strengthened? In addition, what do you see as the downside of a regulatory agency like FDA collecting user fees and what remedies would you propose for the future?

2. Should we continue to have performance goals for the drug and biological review process? If so, how should goals be determined?

3. If user fees fund FDA's drug and biological review processes, what percentage of the program's costs should be covered by fees, and how should those fees be used? The following table shows the percent of drug and biological review spending funded by industry fees since the beginning of PDUFA in 1993:

TABLE 1.

Year	1993	1994	1995	1996	1997	1998	1999
Fee percent	7%	24%	36%	36%	36%	40%	43%

The percent paid from fee revenues is currently estimated to exceed 50 percent of FDA's spending on drug review by 2002.

The following table shows the approximate percent of costs of overall drug regulation paid from industry fees in some other countries:

TABLE 2.

Country	Australia	Canada	United Kingdom
Fee percent	100%	70%	100%

4. Should fees collected from industry be used to pay for other costs FDA incurs to ensure that drugs in the American marketplace are safe and effective? Such additional costs might include monitoring adverse drug reactions, monitoring drug advertising, and routine surveillance, inspection and testing of drug manufacturers.

III. Comments

Interested persons may submit written comments to the Dockets Management Branch (address above), or via e-mail to FDADockets@oc.fda.gov, or via the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/commentsdocket.cfm> by October 31, 2000. Comments are to be identified with the docket number found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Transcripts

You may request a transcript of the PDUFA public meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10

cents per page. You may also examine the transcript of the meeting after September 30, 2000, at the Dockets Management Branch between 9 a.m. and 4 pm., Monday through Friday, as well as on the Internet at <http://www.fda.gov/oc/pdufa2/meeting2000.html>.

Dated: July 25, 2000



William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

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