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Human Resources Division

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February 2, 1994

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
Business Opportunities, and Energy
Committee on Small Business
House of Representatives

Dear Mr. Chairman:

In your letter of February 5, 1993, you expressed concern that the Food and Drug Administration (FDA) may be taking too long to review and approve safety devices designed to protect health care workers from injury and exposure to blood-borne infections. You also raised several questions about the extent to which the Department of Veterans Affairs (VA) is using new and safer needle and sharps devices and whether the cost of these devices has inhibited VA from purchasing them. This letter addresses FDA's process for reviewing safety devices.

In brief, we found that time spent by FDA reviewing applications for these devices increased by 147 percent from fiscal year 1992 to fiscal year 1993, mainly because the FDA branch that reviews these applications experienced significant staff attrition. This, in turn, has caused a backlog of applications awaiting review. FDA has hired additional staff and is attempting to reduce the time it spent in the review process. It has also established a goal of July 1994 for eliminating its backlog.

In a subsequent report, we will address the remaining questions you raised concerning VA's use of safer needle and sharps devices.

Background

The Federal Food, Drug and Cosmetic Act, as amended, requires manufacturers to report to FDA at least 90 days before marketing a new device. Such a report must include a description of the device and whether the manufacturer is claiming that it is substantially equivalent to a device already being marketed. To determine whether a device is substantially equivalent, FDA requires manufacturers of most

medical devices[1] to submit an information package documenting test results and describing the technical specifications of the product. This package is referred to as a "premarket notification." FDA does not conduct clinical trials to assess a device's safety or effectiveness as part of the review process.

Premarket notifications are reviewed by the Office of Device Evaluation (ODE) within FDA's Center for Devices and Radiological Health. The General Hospital Devices (GHD) Branch within ODE[2] reviews applications for new or modified needles, syringes, sharps devices, and certain other medical devices. The purpose of the Branch's review is to determine whether devices are substantially equivalent, in terms of safety and effectiveness, to that of medical devices already being legally marketed in the United States. Devices found to be substantially equivalent are cleared for marketing. The manufacturer must receive a written order from FDA finding the firm's device substantially equivalent and authorizing marketing before beginning commercial distribution of the device.

Medical devices that the Branch finds not substantially equivalent to previously marketed devices were subjected to a more rigorous regulatory process, if the manufacturer still wants to market the device. Since 1991, ODE/GHD has determined that only three needle or sharps devices reviewed under the premarket notification process have not been substantially equivalent to previously marketed devices. In each of these cases, the manufacturers withdrew their applications for premarket notification determination and have not submitted applications for review under the more rigorous testing standards applied to new, unique devices.

Review Times for Sharps Devices Increased in Fiscal Year 1993

The GHD Branch took more time to review premarket notifications for sharps devices in fiscal year 1993 than in fiscal year 1992. During fiscal year 1993, the Branch reviewed 15 premarket notifications. These reviews took an average of 272 days each. This is 162 days more per review than it took to examine 10 similar devices in fiscal year

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[1]FDA has exempted specific medical devices from this requirement. See 21 C.F.R. 862-880.

[2]ODE has five divisions; GHD is one of seven branches in the General and Restorative Devices Division.

1992. (See attachment I.) FDA officials said that the main reason for the increased review times was a lack of sufficient staff to review the manufacturers' documentation. Specifically, the number of reviewers in the GHD Branch decreased from 4.6 full-time equivalents (FTEs) in September 1992 to 1.6 FTEs in June 1993. The attrition was due to voluntary staff transfers within FDA and resignations. FDA did not fill vacancies immediately because it was under a hiring freeze from January 1991 to July 1993.

In addition, FDA's Center for Devices and Radiological Health has directed all its reviewers to more thoroughly document review conclusions. The reviewers, in turn, have required more information from applicants. These strengthened review procedures helped increase the review times. The Center's directive for more thorough documentation was partly in response to a July 1990 Department of Health and Human Services' Inspector General (IG) report[3] that recommended several actions to improve controls over the center's premarket notification review process. The IG report included recommendations such as initiating a more comprehensive documentation policy for review decisions and ensuring that all reviewers apply the "first-in, first-reviewed" policy uniformly.

Reviewers are also paying increased attention to ensuring that applicants use well-designed clinical trials and are requesting additional information on the results of these trials. This is the result of recommendations made in March 1993 by a committee of FDA officials that reviewed selected applications for medical devices. The purpose of this committee was to develop recommendations on how to improve the clinical review process. In its report, the committee found that manufacturers' clinical trials of these devices were not well planned and ignored basic principles of experimental design. Thus, it recommended that ODE reviewers (1) interact with applicants earlier in the review process, (2) develop guidance on study design and analysis, (3) adhere to the principles of sound study design throughout the review, and (4) make better use of advisory committees to help improve the quality of the data submitted in applications.

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[3]See Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Review Process, U.S. Department of Health and Human Services, Office of Inspector General, Pub. No. A-15-89-00065 (Washington, D.C.: July 1990).

Attachment I shows the number of premarket notifications for sharps devices that the GHD Branch received and reviewed and the average length of time it took to complete its reviews. Our examination of 77 applications for sharps devices submitted between January 1, 1990, and September 30, 1993, found that FDA had completed 57 of them.[4] Of the remaining 20 applications, 10 were received in FDA in fiscal year 1992 and 10 in fiscal year 1993.

To determine the causes of lengthy review times, we examined five applications reviewed in fiscal year 1993. These applications had review times averaging 287 days from receipt to the date a review decision was made. Each had long periods of inactivity (averaging 195 days) while the reviewer worked on other tasks. These periods occurred when a reviewer returned an application to a manufacturer with a request to provide additional information and moved on to other applications. Under the "first-in, first-reviewed" policy, manufacturers' submissions of supplemental information are placed in a separate work queue and are not reviewed until the work is done on all applications already in that queue. Analysis of the review process showed, in each case, that the reviewer reached decisions quickly once he or she could concentrate on an application. It also demonstrated the importance of submitting complete data packages initially. While manufacturers took only 17 days, on average, to provide reviewers with additional data for the five applications we reviewed, the delays caused by these applications' losing their places in the queue were as much as 130 days.

Increased review times for applications submitted to the GHD Branch has not been limited to sharps devices. Between fiscal years 1992 and 1993, the average review time for premarket notifications for all types of devices increased from 152 to 275 days or 81 percent. This average review time was slightly higher than the 272 days taken during that period to review sharps devices. Attachment II shows the numbers of premarket notifications for all devices that the GHD Branch received and reviewed, including sharps devices, and the average review times.

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[4]As of September 30, 1993, 20 device applications were either under review by GHD staff or were awaiting additional information from applicants. Review times for these applications averaged 347 days since they arrived in FDA.

FDA Is Trying to Shorten Review Times and Reduce Backlog

ODE has taken action to reduce the review time for notifications. Specifically, in February 1993, it directed reviewers in the GHD Branch to scan each application upon receipt and reject any that lack essential information such as engineering drawings of the device or a summary of safety and effectiveness. Rejected applications are returned to the applicant with FDA review requirements attached to help the manufacturer to revise its premarket notification. This process is designed to reduce the overall time an application remains in the review process. Specifically, this early review gives the manufacturer an opportunity to revise its application, if necessary, soon after the initial submission arrives in FDA rather than the application's waiting in a queue until previously submitted applications are reviewed. The Center for Devices and Radiological Health published draft guidelines for this procedure for all reviewing branches in June 1993. In addition to process changes, FDA hired three additional staff members for the GHD Branch, including a new branch chief who began work in November 1993.

In March 1993, FDA issued detailed guidance specifically on premarket notifications for intravascular catheters and piston syringes. FDA is currently drafting guidance concerning sharps protection devices. In addition, FDA's Division of Small Manufacturers Assistance has helped explain these changes to manufacturers by conducting workshops, answering telephone requests, and issuing guidance and other documents. FDA hopes that these efforts will expedite its reviews by helping manufacturers to submit more acceptable applications, thereby reducing requests by FDA for additional data.

In discussing the results of our work with FDA officials, they told us that they agree with our findings and plan to eliminate the backlog within 6 months (July 1994).

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We will apprise your staff of our progress in responding to your questions about VA's use of safe sharp devices. If you have any questions on the information provided in this correspondence, please contact me at (202) 523-7101.

Sincerely yours,

David P. Baine

David P. Baine
Director, Federal Health Care
Delivery Issues

ATTACHMENT I

ATTACHMENT I

SUMMARY OF PREMARKET NOTIFICATIONS FOR SHARPS DEVICES REVIEWED BY FDA's GENERAL HOSPITAL DEVICES BRANCH, FISCAL YEARS 1990 TO 1993

Fiscal year	Premarket notifications received	Premarket notifications completed	Average days to complete	In process, end of year
1990	15	6[5]	112	9
1991	20	26	77	3
1992	29	10	110	22
1993	13	15	272	20
1992-1993 Percentage change	-55%	+50%	+147%	-9%

[5]Excludes applications received before January 1, 1990.

ATTACHMENT II

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SUMMARY OF ALL PREMARKET NOTIFICATIONS REVIEWED BY FDA's GENERAL HOSPITAL DEVICES BRANCH, FISCAL YEARS 1990 TO 1993

Fiscal year	Premarket notifications received	Premarket notifications completed	Average days to complete	In process, end of year
1990	588	1,065[6]	124	248
1991	523	517	96	254
1992	713	418	152	549
1993	733	510	275	772
1992-1993 Percentage change	+3%	+22%	+81%	+41%

[6]Includes (1) a backlog of many applications for which applicants had failed to provide necessary information and (2) class I devices now exempt from submitting premarket notifications.

ATTACHMENT III

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SUMMARY OF ALL PREMARKET NOTIFICATIONS REVIEWED BY FDA, FISCAL YEARS 1990 TO 1993

Fiscal year	Premarket notifications received	Premarket notifications completed	Average days to complete	In process, end of year
1990	5,831	6,197	98	1,900
1991	5,770	5,367	102	2,291
1992	6,509	4,862	126	3,951
1993	6,298	5,077	195	5,164
1992-1993 Percentage change	-3%	+4%	+55%	+31%

(Code 101440)