〔招待講演〕

“MDR Regulations and the Postmarket Surveillance Studies Section of SMDA 90”

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In this presentation, I will present an overview of the center for Device and Radiological Health's postmarket activities and authorities. Those postmarket activities encompass both the MDR regulation(s) and the postmarket surveillance studies section of SMDA 90, section 522.

In the first part of this presentation, I will provide information on those aspects of the MDR regulation proposed in November 1991 which are unlikely to change in the final review and clearance processes. In the latter part, I will provide an overview of the provisions of Required and Discretionary Postmarket Surveillance Studies authority, section 522 of the SMDA 90.

The SMDA 90 includes a number of statutory provisions which are currently in effect even without a final regulation. Those provisions include user facility reporting with semiannual summary reporting and a 10 day timeframe for reporting individual events; annual certification for distributors, and the definitions for the types of events to be reported. In addition, the statute stipulates to whom reports are to be submitted. For example, user facilities report deaths to both FDA and the device manufacturer whereas reports of serious injuries are submitted only to the manufacturer, if identifiable.

The user facility regulation includes definitions necessary for compliance with its requirements, administrative requirements such as the addresses for FDA, instructions for numbering and submitting reports. The use of certain forms is included as part of the regulation as is the proposed 30 day reporting cycle for manufacturers.

Some of the definitions in the regulation include the events to be reported: deaths, serious injuries and, for distributors and manufacturers, malfunctions which could lead to deaths or serious injuries.

The definition of a user facility will be included in the regulation. User facilities include hospitals, nursing homes, ambulatory surgical facilities, and outpatient diagnostic and treatment facilities. Physician's offices are exempt from mandatory reporting and it is likely that singular single practitioner offices will fall under this exemption. Previously, health care providers, were encouraged to report device-related problems to the voluntary Problem Reporting Program, the PRP, but were under no statutory requirement to report. The voluntary program has been superseded by the FDA MedWatch program and user facilities are now required by law to report device related adverse events.

A number of additional definitions are expected to appear in the final regulation in response to comments made to the November 1991 proposal.

The proposed new regulation will emphasize the public health aspects of postmarket safety data analysis. It encourages more extensive investigation of reported device problems by manufacturers, such as the 30 reporting cycle. The investigation of events is expected to identify unexpected or unanticipated events, events which were not predicted based on the premarket data, marketing experience or knowledge of the clinical use of the device.

Manufacturers will be expected to submit baseline reports on each unique device which will be updated annually.

One of the major changes provided for under the Safe Medical Devices Act of 1990 (SMDA 90), and which becomes a requirement on the effective date of the proposed regulation, is the designation of specific forms for reporting MDRs. The FDA Form 3500 A, also known as the MedWatch mandatory reporting form, will be required for each event reported to FDA and to the manufacturer. In the past, MDR data elements were specified by regulation, but no form was required for submitting those data elements. Other forms will also be required for reporting certification, for baseline reporting, and semi-annual reporting. In addition, FDA is working to permit electronic submission of MDR data.

As I mentioned, the schemes for submitting reports are provided for in the statute. I will review those reporting pathways and indicate for you the timeframes which are either required by law or proposed by regulation. The overall framework looks like this: User facilities report deaths to FDA and to the manufacturer. Serious injuries are to be reported from the user facility to the manufacturer, or to FDA if the manufacturer cannot be identified. Distributors must report deaths, serious injuries and malfunctions which could result in death or serious injury to both FDA and the manufacturer. Manufacturers then are required to investigate all events reported to them and determine if their device caused or may have caused or contributed to the event. Events which meet those criteria (caused, may have caused or contributed) must then be reported to FDA within 30 days of receipt of the initial report.

The timeframes for reporting are as follows. User facilities must report events within 10 days of becoming aware that a reportable event has occurred. Distributors will likely be under a 10 day time clock to report because they are not obligated to conduct the level of investigation required of manufacturers. Manufacturers must submit a report to FDA within 30 days of becoming aware of a reportable event.

One of the features of the new regulation is that FDA will continue to require reports of problems with marketed devices even if the problem appears to be attributable to user error. The Agency's philosophy is that user error may contribute information to the manufacturer and the FDA concerning device design, labeling or possible unintended clinical applications, all of which may be helpful to both the the agency and the manufacturer in assessing public health problems.

Foreign manufacturers of devices cleared for marketing within the US must designate an agent to serve as the focal point for MDR responsibilities. They will be under a 30 day time clock and will be expected to comply with the same requirements as domestic device manufacturers.