amendments (Pub. L. 102–300), amending certain provisions of section 519 of the act relating to reporting of adverse device events. In the future, FDA will publish a proposed rule to fully implement its authority under the 1992 amendments. A summary of these changes follows:

1. Adoption of a Single Reporting Standard

Section 5(a) of the 1992 amendments adopts a single standard to specify when injuries caused by devices must be reported to FDA. Manufacturers and importers are required to report a device-related adverse event to FDA whenever they receive or otherwise become aware of information that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and that such device or a similar device marketed by them would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Similarly, section 5(a) of the 1992 amendments revises the reporting requirements to require a user facility to report whenever the facility receives or otherwise becomes aware of information that reasonably suggests that a device ''has or may have caused or contributed'' to the death, serious illness or serious injury of a patient of the facility.

2. Single Definition of Types of Injuries That Must Be Reported

Section 5(a) of the 1992 amendments also adopted a single definition for the types of injuries that user facilities, manufacturers, importers, and distributors must report. This definition requires reporting of an injury or illness that is: (1) Life-threatening; (2) results in permanent impairment of a body function or permanent damage to a body structure; or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. This definition differs from the previous statutory definition of ''serious injury'' or ''serious illness'' in the user facility provisions and the definition in the November 1991 tentative final regulation. The new definition deleted the requirement that an injury must require immediate intervention to preclude permanent impairment or damage in order to qualify as a reportable adverse event.

3. New Authority To Require Reporting of ''Other Significant Adverse Device Experiences''

The 1992 amendments also authorized FDA to issue regulations requiring user facilities, manufacturers, importers, and distributors to report ''significant adverse device experiences'' that the agency determines are necessary to be reported, other than deaths, serious injuries or serious illnesses, that might otherwise not fall within the definitions of reportable deaths, serious injuries, or malfunctions.

III. Reporting Forms

A. Individual Adverse Event Reports by User Facilities and Manufacturers

Under §§ 803.30 and 803.50, user facilities and manufacturers are required to submit device-related reports of individual adverse events on FDA Form 3500A or an FDA approved electronic equivalent. In order to simplify and consolidate reporting of adverse events, FDA announced in the Federal Register of February 26, 1993 (58 FR 11768) the availability of a new single ''MEDWATCH'' form for reporting adverse events and product problems with devices, drugs, biologics, special nutritional products and other products regulated by the agency (hereinafter referred to as the February 1993 notice). In response to FDA's request for comments on the form in the Federal Register, 79 comments were submitted by medical device trade associations and other regulated or affected entities. On June 3, 1993 (58 FR 31596), after consideration of these comments, FDA published the final reporting form. (The form is described in § 803.10.)

B. Annual Certification by Manufacturers

Under § 803.57, manufacturers must also submit at the time of their annual registration a completed FDA Form 3381 or an FDA approved electronic equivalent, certifying: (1) That all reportable events were submitted; (2) the number of reports submitted; or (3) that no reports were submitted during the previous 12-month period.

C. Semiannual Summaries by User Facilities

Under § 803.33, user facilities are required to submit, on FDA Form 3419 or an FDA approved electronic equivalent, a semiannual summary of all events reported during the prior reporting period. Semiannual reports must include information regarding the user facility, device manufacturers, products, and a brief description of the events.

D. Baseline Reports

Under § 803.55, manufacturers must submit baseline reports, on FDA Form 3417 or an FDA approved electronic equivalent, simultaneously with the submission of the first event report for each device. These reports, which are to be updated annually, must contain information on the manufacture and distribution of the relevant devices.

E. Effective Date of the Reports

Adverse event reports and other related reports required by this regulation must be submitted using the appropriate forms or approved electronic equivalents, after April 11, 1996.

IV. Summary and Analysis of Comments and FDA's Response

This final rule is based on FDA's analysis of the over 300 comments that the agency received in response to the November 1991 tentative final rule, and it conforms to certain statutory revisions in the 1992 amendments. This final rule reflects actions in two areas. First, it revises the manufacturer reporting regulations that have been in effect since 1984. Second, it implements the statutorily directed user facility reporting requirements that have been in effect since November 28, 1991.

Originally, FDA gave interested persons until January 27, 1992, to comment on the November 1991 tentative final rule. In the Federal Register of January 24, 1992 (57 FR 2861), FDA extended the comment period until February 26, 1992. A summary of the comments and FDA's responses follow:

A. Section 803.1—Scope

1. Several comments stated that the proposed regulation exceeds the SMDA and has no statutory authority. Many comments stated that the scope of the provisions was overly broad, and would increase the burdens, with unclear benefits, on all parties involved.

The agency disagrees. Section 519 of the act, as amended by the SMDA and the 1992 amendments, provides clear authority to issue this regulation. Section 519 of the 1976 amendments granted FDA the authority to issue regulations to require manufacturers to maintain such records, make such reports, and provide such information to FDA as may reasonably be necessary to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. The legislative history of the 1976