

Vaccine Injury Act (NCVIA) of 1986. Those mandatory reports are submitted by physicians to the joint FDA/Centers for Disease Control and Prevention (CDC) Vaccines Adverse Event Reporting System (VAERS) on the VAERS-1 form (see <http://www.vaers.org> for pdf version) rather than the FDA 3500 or 3500A forms.

Hospitals are not required by Federal law or regulation to submit adverse event reports, product problems, or medication errors associated with medications, biological products or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device related deaths and serious injuries.

Manufacturers of dietary supplements do not have to prove safety or efficacy of their products prior to marketing, nor do they have mandatory requirements for reporting adverse reactions to FDA. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. The agency is dependent on the voluntary reporting by health professionals and consumers of suspected adverse events associated with the use of dietary supplements.

III. Use of the Mandatory Version (FDA Form 3500A)

A. Drug and Biologic Products

In sections 505(j) and 704 (21 U.S.C. 374) of the act, Congress has required that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and 600 (biologics). Parts 310, 314, and 600 mandate the use of the FDA Form 3500A form for reporting to FDA on adverse events that occur with drug and biologics.

[Note: Most pharmaceutical manufacturers already use a one-page modified version of the 3500A form where Section G from the back of the form is substituted for Section D on the front of the form.]

B. Medical Device Products

Section 519 of the act (21 U.S.C. 360i) requires manufacturers and importers of devices intended for human use to establish and maintain records, make reports, and provide information as the

Secretary of Health and Human Services may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. Furthermore, the Safe Medical Devices Act of 1990 (SMDA), signed into law on November 28, 1990, amends section 519 of the act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 mandates the use of the FDA Form 3500A for reporting to FDA on medical devices.

C. Other Products Used in Medical Therapy

There are no mandatory requirements for the reporting of adverse events or product problems with products such as dietary supplements.

FDA estimates the burden for completing the forms for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Center (21 CFR Section)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Biologics Evaluation and Research/ Center for Drug Evaluation and Research Form 3500	20,074	1	20,074	0.5	10,037
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80)	600	463.86	278,315	1.0	278,315
Center for Devices and Radiological Health Form 3500	3,252	1	3,252	0.5	1,626
Form 3500A (§ 803)	1,935	33	63,623	1.0	63,623
Center for Food Safety and Applied Nutrition Form 3500	895	1	895	0.5	448
Form 3500A (no mandatory requirements)	0	0	0	1.0	0
Total Hours					354,049
Form 3500					12,111
Form 3500A					341,938

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

NOTE: FDA Form 3500 is for voluntary reporting; FDA Form 3500A is for mandatory reporting.

The figures shown in Table 1 of this document are based on actual fiscal year 2002 reports and respondents for each Center and type of report.

IV. Electronic Access

Persons with access to the Internet may obtain the MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory) at <http://www.fda.gov/medwatch/getforms.htm> or by calling 1-800-FDA-1088 and

leaving your name and mailing address. Copies of the MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory) are available for public examination at <http://www.fda.gov/ohrms/dockets/dockets/dockets.htm> or in the Dockets