limits on the amounts of necessary medical and remedial care expenses recognized under State law but not covered under the State plan. However, those reasonable limits must ensure that nursing home residents are able to use their own funds to purchase necessary medical or remedial care not covered; *i.e.*, not paid for, by the State Medicaid program.

The SPA 05–06 proposes to limit the deduction of medical expenses to those incurred only during a period of eligibility for Medicaid. Thus, an individual who incurred medical expenses during the 3-month period prior to the date of application would not have any protection under the post-eligibility calculation for medical expenses incurred during that period unless he or she were determined to be eligible during that period.

In discussions with State Medicaid program staff, we confirmed this is the intent of the proposed amendment. While we believe some limitations imposed on the age of an incurred expense could be considered reasonable, we do not believe it would be reasonable for a State to exclude from post-eligibility protection an incurred medical expense that could be deducted from a person's income under the medically needy spenddown process. While the medically needy spenddown rules in Federal regulations at 42 CFR 435.831(g)(2) permit States to exclude expenses incurred earlier than 3 months before the month of application, Maryland proposes to only permit deduction under its post-eligibility process for expenses incurred while an individual is actually eligible for Medicaid.

The State's limitation would result in an individual being able to use certain incurred medical expenses to establish eligibility for Medicaid, but not being able to deduct those same expenses under the post-eligibility process. While the statute permits the State to establish reasonable limits on the amount of non-covered expenses, we do not believe the limit is reasonable if the result were to deny the individual the ability to pay for a non-covered expense used to establish eligibility during a budget period.

The intent of section 1902(r)(1) of the Act is to afford an institutionalized individual with income the ability to actually pay non-covered medical expenses for medical and remedial care. Section 1902(r)(1) of the Act was added to the Medicaid statute by the Medicare Catastrophic Coverage Act of 1988. The Conference Report explains it was enacted to reinstate policies set forth previously in Medicaid regulations before they were revised by the Department of Health and Human Services in February 1988. Under that revised regulation, Maryland would have had the authority to implement the limits it proposes in SPA 05–06. However, by enacting section 1902(r)(1) of the Act, Congress specifically rejected that approach.

Moreover, by not protecting income to pay for non-covered expenses which were used to establish eligibility under the medically needy spenddown, the State's proposed amendment undercuts the Medicaid statute's purpose of requiring States to deduct incurred expenses under the spenddown process. To the extent that Maryland's amendment fails to protect income to enable the individual to actually pay for these incurred expenses, we view the State's proposed limit as not being reasonable. As a result, we believe the limit does not meet the requirements of section 1902(a)(17) of the Act, as refined by section 1902(r)(1) of the Act. For individuals whose post-eligibility calculation is determined using the spousal impoverishment rules, specified at section 1924 of the Act and refined by section 1902(r)(1) of the Act, we believe the limit does not meet the requirements of section 1902(a)(51) of the Act, which requires the State plan to meet the requirements of section 1924 of the Act.

Based on the reasoning set forth above, and after consulting with the Secretary as required by Federal regulations at 42 CFR 430.15(c)(2), the Centers for Medicare & Medicaid Services (CMS) disapproved Maryland Medicaid SPA 05–06.

I am scheduling a hearing to be held on September 15, 2005, at 12:00 Noon in CMS'' Philadelphia Regional Office, in the Virginia Room 229;150 S. Independence Mall, West; Suite 216; Philadelphia, Pennsylvania 19106, to reconsider our decision to disapprove Maryland's SPA 05–06. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, part 430.

The issues to be considered during the hearing are whether the amendment's limit violates the requirements of sections 1902(a)(17) and 1902(a)(51) of the Act by imposing an unreasonable limit on expenses for medical and remedial care which will be protected under the post-eligibility process.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,

*Mark B. McClellan, M.D., Ph.D.*

Section 1116 of the Social Security Act (42 U.S.C. section 1316); 42 CFR section 430.18.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program.)

Dated: July 19, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 05–16304 Filed 8–12–05; 1:32 pm]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0535]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: Food and Drug Administration Medical Products Reporting Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by September 15, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### MedWatch: FDA Medical Products Reporting Program, Form FDA 3500 and Form FDA 3500A—(OMB Control Number 0910–0291)—Extension

Under sections 505, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 360b, 360c, 360e, and 393), and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act (21 U.S.C. 352(f)(1)), it is misbranded if it fails to bear adequate warnings, and under section 502(j) of the act (21 U.S.C.

352(j)), it is misbranded if it is dangerous to health when used as directed in its labeling.

Under section 4 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) (21 U.S.C. 341), section 402 of the act (21 U.S.C. 342) is amended so that FDA must bear the burden of proof to show a dietary supplement is unsafe.

To carry out its responsibilities, the agency needs to be informed whenever an adverse event, product problem, or error with use of a medication or device occurs. Only if FDA is provided with such information will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce or eliminate the public's exposure to the risk through regulatory action. To ensure the marketing of safe and effective products, certain adverse events must be reported. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, 803, and 1271 (21 CFR parts 310, 314, 600, 803, and 1271), specifically §§ 310.305, 314.80, 314.98, 314.540, 600.80, 803.30, 803.50, 803.53, 803.56, and 1271.350(a).

To implement these provisions for reporting of adverse events, product problems, and medication/device use errors for FDA regulated products such as medications, devices, biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps), special nutritional products, and cosmetics, as well as any other products that are regulated by FDA, two forms are available from the agency. Form FDA 3500 may be used for voluntary (i.e., not mandated by law or regulation) reporting by healthcare professionals and the public. Form FDA 3500A is used for mandatory reporting (i.e., required by law or regulation).

Respondents to this collection of information are healthcare professionals, hospitals and other user facilities (e.g., nursing homes, etc.), consumers, manufacturers of biological and drug products or medical devices, and importers.

## II. Use of Form FDA 3500 (Voluntary Version)

The voluntary version of the form is used to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required by law or regulation to submit reports to the agency or the manufacturer, with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Those mandatory reports are not submitted to FDA on Form FDA 3500 or Form FDA 3500A, but are submitted to the joint FDA/Centers for Disease Control and Prevention Vaccines Adverse Event Reporting System (VAERS) on the VAERS–1 form. (See *http://www.vaers.hhs.gov*.) (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, 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 mandatory requirements for reporting adverse reactions to FDA. DSHEA puts the responsibility on FDA to prove that a particular product is unsafe. The agency depends on the voluntary reporting by health professionals and consumers of suspected adverse events associated with the use of dietary supplements.

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

### *A. Drug and Biologic Products*

In sections 505(j) and 704 of the act (21 U.S.C. 355(j) and 374), 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 (New Drugs) and 314 (Applications for FDA Approval to Market a New Drug), 600 (Biological Products: General), and 1271 (Human Cells, Tissues, and Cellular and Tissue-Based Products). Parts 310, 314, 600, and 1271 mandate the use of Form FDA 3500A for reporting to FDA adverse events that occur with drugs and biologics.

### *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 their safety and effectiveness.

The Safe Medical Device Act of 1990, signed into law on November 28, 1990, amends section 519 of the act (21 U.S.C. 360i). 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 Form FDA 3500A for reporting to FDA on medical devices.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107–250, signed into law October 26, 2002, amended section 519 of the act. The amendment (section 303 of MDUFMA) requires FDA to revise the MedWatch forms to facilitate the reporting of information relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.

## IV. Proposed Modifications to Forms

The proposed modifications to Form FDA 3500 and Form FDA 3500A reflect changes that will bring the forms into conformation with current regulations, rules, and guidances. Modifications were also made to better reflect the range of reportable products and language was changed slightly to provide clarity. The changes should allow reporters to better utilize available space for data entry and offer voluntary reporters the opportunity to better characterize the suspected adverse event, product problem or error, and provide better quality safety-related data for agency evaluation.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| FDA Center(s) (21 CFR Section) | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Center for Biologic Evaluation and Research/Center for Drug Evaluation and Research | | | | | |
| Form FDA 3500[2] | 23,867 | 1 | 23,867 | 0.6 | 14,320 |
| Form FDA 3500A (310.305, 314.80, 314.98, and 600.80) | 600 | 579.9 | 401,390 | 1.1 | 441,529 |
| Center for Devices and Radiological Health | | | | | |
| Form FDA 3500[2] | 3,717 | 1 | 3,717 | 0.6 | 2,230 |
| Form FDA 3500A (part 803)[3] | 1,919 | 40 | 76,203 | 1.1 | 83,823 |
| Center for Food Safety and Applied Nutrition | | | | | |
| Form FDA 3500[2] | 665 | 1 | 665 | 0.6 | 399 |
| Form FDA 3500A (No mandatory requirements)[3] | 0 | 0 | 0 | 1.1 | 0 |
| Form FDA 3500[2] | | | | | 16,949 |
| Form FDA 3500A[3] | | | | | 525,352 |
| Total Hours | | | | | 542,301 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Form FDA 3500 is for voluntary reporting.
[3] Form FDA 3500A is for mandatory reporting.
(NOTE: The figures shown in table 1 are based on actual calendar year 2004 reports and respondents.

**V. Agency Response to Comments**

In the **Federal Register** of December 27, 2004 (69 FR 77256), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received several comments; the majority addressed revisions to Form FDA 3500A.

Several pharmaceutical manufacturers expressed concern over FDA's revision of mandatory Form FDA 3500A since FDA encourages electronic submission of postmarketing adverse event reports, and it would be an unfair burden to manufacturers who submit electronically to expend resources to change the form which would be used only in times of rare network or server outages. FDA disagrees with this comment. As described in a May 2001 draft guidance entitled ''Providing Regulatory Submissions in Electronic Format Postmarketing Expedited Safety Reports'', manufacturers can send individual case safety reports (ICSRs) to FDA using either FDA's electronic data interchange (EDI) gateway or physical media (such as CD–ROM or digital tape). If the EDI gateway is not functional, regulatory requirements can be met by submitting ICSRs on physical media.

A number of manufacturers commented that certain sections of proposed Form FDA 3500A were based on proposed rules, regulations, and guidances. They noted that considerable resources would be required to modify computer systems and processes, and changes to the form should be based on current rules, regulations, and guidances. Likewise, such changes should be consistent with current International Conference on Harmonization (ICH) guidelines. FDA agrees with these comments and has based the final revised Form FDA 3500A on current rules, regulations, and guidances to the extent possible. Proposed reformatting of Form FDA 3500A has also been minimized based on these comments. In addition, to allow mandatory reporters time to make the necessary changes to their computer systems and processes to conform to the revised Form FDA 3500A , FDA is granting a grace period of 1 year. During this transition period FDA will accept both the newly effective Form FDA 3500A and the prior version of the form.

Device manufacturers commented that there were unnecessary changes made to the form pertaining only to device reporting. FDA agrees and has minimally altered the device sections of the final forms. FDA additionally recognizes the burden this places on device manufacturers as they were recently required to make computer and process changes based on the modified Form FDA 3500A as mandated by MDUFMA.

Some comments noted that FDA underestimated the burden of the proposed collection of information, only capturing time required to complete the form and not capturing the significant resources required to modify and validate the forms. One drug manufacturer estimated that 50 to 60 hours per computerized system would be required to modify and validate the changes to the form. FDA acknowledges these comments and has made an effort to modify Form FDA 3500A to the minimum extent possible to conform with current rules, regulations, and guidances in order to minimize this burden to industry.

Several comments noted that FDA did not include instructions to revised Form FDA 3500 and Form FDA 3500A, which resulted in a lack of clarity in modified sections and lack of definition regarding newly added terminology. FDA acknowledges these comments. Both the previous and newly revised Form FDA 3500A along with the newly revised voluntary Form FDA 3500, with instructions for both forms, will be made available upon OMB approval on FDA's MedWatch Web site at *http://www.fda.gov/medwatch/getforms.htm*.

One comment requested consistency in formatting of dates throughout both forms. FDA agrees and has conformed to a mm/dd/yyyy format throughout both forms.

FDA proposed several changes to section B.2 (Outcomes Attributed to Adverse Event) of both forms. A number of comments were received regarding this proposal. The ''Not Serious'' and ''No Harm'' checkboxes elicited comments that clarification was required regarding when these boxes would be used, and that these boxes do not conform to any current rules, regulations, or guidances, including

current ICH guidances. FDA agrees with these comments and the ''Not Serious'' and ''No Harm'' checkboxes do not appear on the final Form FDA 3500 and Form FDA 3500A. Another proposed checkbox was ''Important Medical Events''. This checkbox has been revised on the final Form FDA 3500 and Form FDA 3500A to ''Other Serious (Important Medical Events)''. This new terminology is consistent with the definition of ''Serious'' in 21 CFR 310.305, 312.32, 314.80, and 600.80 as well as ICH E2A guidelines. In addition, the outcome ''Required Intervention to Prevent Permanent Impairment/ Damage'' has been revised, adding ''(devices)'' at the end of the term. Additional detail has been provided in the revised instructions to provide more clarity for the use of section B.2 of both forms.

In section B.5 of both forms, the proposed checkboxes ''Product Used During Pregnancy'' and ''Product Used During Breast Feeding'' produced concern as these new data fields introduce divergence from ICH standards and appear to duplicate information that is usually provided in the narrative section and in coded adverse event terms. FDA agrees and has not included these checkboxes in the final forms. As a result, the term ''Pregnancy'' has been returned to the examples in section B.7 (Other Relevant History) on both Form FDA 3500 and Form FDA 3500A.

A few comments noted the removal of the term ''if known'' from several fields of the forms and questioned this action as a new requirement for these data. The final forms do not contain the term ''if known'' in any of the fields for reasons of form consistency. This should not be interpreted as a new requirement. If information is not known for any of the fields, they should be left blank. This is reflected in the revised instructions.

Several comments questioned the addition of the Unique Identifier Number (Unique ID) to proposed section D.9 of both forms. Unique ID is required under § 1271.350 for reporting of adverse events for HCT/Ps.

One comment recommended the addition of ''Solicited'' and ''Spontaneous'' checkboxes to Form FDA 3500A. FDA has not accepted this recommendation. As described in an August 1997 guidance for industry entitled ''Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report,'' information concerning potential adverse experiences derived during planned contacts and active solicitation of information from patients should be handled as safety information obtained from a postmarketing study. Section G of the previous and revised Form FDA 3500A contains a checkbox for ''Study'' which captures such information.

One comment requested that FDA include information on drug name, dose, frequency, route, dates of diagnosis for use, and event abated/ reappeared after reintroduction on one line of Form FDA 3500 and Form FDA 3500A. FDA disagrees since these changes would decrease form clarity and would require costly and unnecessary computer and process revisions.

One comment noted that the MedWatch program needs to do the following: (1) Enhance the quality, utility, and clarity of information to be collected; (2) data entry accuracy needs to be improved; and (3) the public version of the adverse events database needs to be posted in a timely manner, and FDA needs to vigorously enforce mandatory reporting requirements. FDA acknowledges these comments regarding FDA programs and processes. However, the comment did not suggest specific changes to Form FDA 3500 or Form FDA 3500A .

In the final versions of Form FDA 3500 and Form FDA 3500A, there are some differences. FDA proposed adding two checkboxes to section B.1: ''Product Use Error'' and ''Product Switch''. Since there is currently no requirement to report medication, device, or other regulated product errors, these boxes do not appear on the final version of Form FDA 3500A . However, ''Product Use Error'' will be included on the voluntary Form FDA 3500, as the agency has become aware that voluntary reporters who wish to submit medication and other product use errors to FDA are not certain that Form FDA 3500 can be used for this purpose. FDA encourages voluntary reporting of product use errors.

The ''Product Switch'' checkbox does not appear on the final Form FDA 3500A , however, a revised checkbox ''Problem with different manufacturer of same medicine,'' does appear on Form FDA 3500 to enable voluntary reporters to more clearly submit reports directly to FDA that involve adverse events or product problems related to brand-to-generic, generic-to-brand, one generic to another generic, or other therapy changes relating to the same active ingredient produced by different manufacturers.

FDA proposed reformatting changes in sections A and D of both forms to conserve space on the forms. These changes do not appear on the final Form FDA 3500A; however, section D (Suspect Product(s)) of revised Form FDA 3500 is modified. FDA believes the collection of data in specific boxes for dose/amount, frequency, and route increases clarity and enhances the likelihood that these data would be obtained from consumers and healthcare professionals who voluntarily submit reports directly to FDA.

Several comments were received on new section C (Product Availability). Pharmaceutical manufacturers expressed concern that the practice of obtaining, storing, and analyzing returned products would significantly impact their working practice and goes beyond current regulations and guidances. FDA agrees with these comments and the ''Product Availability'' question has been returned to the ''Suspect Medical Device'' section of Form FDA 3500A . However, the revised voluntary Form FDA 3500 contains the new section C, to enable FDA to collect such information particularly for products that currently do not have mandatory adverse event reporting requirements, such as special nutritional products and cosmetics.

Dated: August 9, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–16141 Filed 8–15–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005N–0218]**

### Vision 2006—A Conversation With the American Public; Notice of Public Meetings on Specific Food and Drug Administration Issues; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meetings; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a series of public meetings entitled ''Vision 2006—A Conversation With the American Public,'' in three cities. This forum will be an open format in which consumers can interact directly with the agency's leadership to discuss what is on the public's mind. It will also be an opportunity for the agency to update the public on current agency programs, engage the public in discussion, and obtain consumer input on specific