Dated: November 3, 1998.

Donald Sykes,

Director, Office of Community Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0393]

Agency Information Collection Activities; Proposed Collection; MedWatch: The FDA Medical Products Reporting Program; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed revision of two forms for collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed revision of two forms from ''MedWatch: The FDA Medical Products Reporting Program'' (MedWatch). These forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), will be used to report to the agency on adverse events and product problems that occur with all medical products regulated by FDA.

DATES: Submit written comments on the collection of information by January 11, 1999.

ADDRESSES: Submit written requests for single copies of the revised MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), and a summary of the proposed revisions to the forms, by e-mail to ''medwatch@oc.fda.gov'', by fax to 301–827–7241, or by mail to ''MedWatch: The FDA Medical Product Reporting Program,'' Food and Drug Administration (HF–2), 5600 Fishers Lane, rm. 17–65, Rockville, MD 20857 (301–827–7240). Requests by mail should include one self-addressed adhesive label to assist that office in processing your request. Copies of the forms and the summary of the changes may also be obtained via Internet at ''http://www.fda.gov/medwatch'' under ''How to Report''.

Submit written comments on the revised MedWatch reporting forms to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

MedWatch—The FDA Medical Products Reporting Program (Forms FDA 3500 and FDA 3500A) (OMB Control Number 0910–0291—Revision)

Under sections 505, 507, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 357, 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 it is misbranded if it fails to bear adequate warnings, and under section 502(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 (the DSHEA) (21 U.S.C. 301), 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 or product problem 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 ranging from labeling changes to the rare product withdrawal. 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, and 803 (21 CFR 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, and 803.56.

To implement these provisions for reporting of adverse events and product problems with all medications, devices, and biologics, as well as any other products that are regulated by FDA, two very similar forms are used. Form FDA 3500 is used for voluntary (i.e., not mandated by law or regulation) reporting of adverse events and product problems by health 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 health professionals, hospitals and other user-facilities (e.g., nursing homes, etc.), consumers, manufacturers of biologics, drugs and medical devices, distributors, and importers.

II. Use of the Voluntary Version (FDA Form 3500):

Individual health professionals are not required by law or regulation to submit adverse event or product problem reports to the agency or the manufacturer. There is one exception. The National Childhood Injury Act of 1986 mandates that certain adverse reactions following immunization be reported by physicians to the joint FDA/Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS).

Hospitals are not required by Federal law or regulation to submit adverse event reports on medications. However, hospitals and other medical 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 of 1994 puts the onus on FDA to prove that a particular product is unsafe. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements.

The voluntary version of the form is used to submit all adverse event and product problem reports not mandated by Federal law or regulation.

Experience over the past 5 years has revealed the need to modify the voluntary form to better utilize the available space and to better query reporters for information specific to dietary supplements and medication quality problems.

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

A. Drug and Biologic Products

In section 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 part 600 (biologics) of the Code of Federal Regulations. Parts 310, 314, and 600 mandate the use of the FDA Form 3500A for reporting to FDA on adverse events that occur with drugs and biologics.

B. Medical Device Products

Section 519 of the act (21 U.S.C. 360i) requires manufacturers, importers, or distributors 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 ensure that such devices are not adulterated or misbranded and to otherwise ensure its safety and effectiveness. Furthermore, the Safe Medical Device Act of 1990, 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 21 CFR part 803 (part 803). Part 803 mandates the use of 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. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements.

The mandatory form has been modified to incorporate some new data elements and to allow drug and biologic manufacturers to use only the front page rather than the full two-page form. (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.)

IV. Estimated Reporting Burden

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center(s)[1] and Forms (with applicable 21 CFR Section)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER					
Form 3500[2]	16,008	1	16,008	0.5	8,004
Form 3500A[3] (§§ 310.305, 314.80, 314.98, and 600.80)	410	573.9	235,304	1.0	235,304
CDRH					
Form 3500[2]	2,353	1	2,353	0.5	1,176.5
Form 3500A[3] (§ 803)	3,116	24.8	77,337	1.0	77,337
CFSAN					
Form 3500[2]	237	1	237	0.5	118.5
Form 3500A[3] (no mandatory requirements)	0	0	0	1.0	0
Total Hours					321,940
Form 3500[2]					9,299
Form 3500A[3]					312,641

[1] CBER (Center for Biologics Evaluation and Research), CDER (Center for Drug Evaluation and Research), CDRH (Center for Devices and Radiological Health), and CFSAN (Center for Food Safety and Applied Nutrition).
[2] FDA Form 3500 is for voluntary reporting.
[3] FDA Form 3500A is for mandatory reporting.

The figures shown in Table 1 of this document are based on actual number of calendar year 1997 reports and respondents for each center and type of report.

As more medical products are approved by FDA and marketed, and as knowledge increases regarding the importance of notifying FDA when adverse events and product problems are observed, it is expected that more reports will be submitted.

V. Request for Comments

Interested persons may, on or before January 11, 1999, submit written

comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and copies of the revised MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30007 Filed 11–9–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0228]

Determination of Regulatory Review Period for Purposes of Patent Extension; Neuro Cybernetic Prosthesis (NCP®) System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Neuro Cybernetic Prosthesis (NCP®) System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Neuro Cybernetic Prosthesis (NCP®) System. Neuro Cybernetic Prosthesis (NCP®) System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures, which are refractory to antiepileptic medications. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Neuro Cybernetic Prosthesis (NCP®) System (U.S. Patent No. 4,867,164) from Cyberonics, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 22, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Neuro Cybernetic Prosthesis (NCP®) System represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Neuro Cybernetic Prosthesis (NCP®) System is 3,237 days. Of this time, 3,066 days occurred during the testing phase of the regulatory review period, while 171 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: September 6, 1988. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on November 15, 1988. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on September 6, 1988, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: January 27, 1997. The applicant claims December 16, 1991, as the date the premarket approval application (PMA) for Neuro Cybernetic Prosthesis (NCP®) System (PMA 910070) was initially submitted. However, FDA records indicate that PMA 910070 submitted on December 6, 1991, was incomplete. FDA refused this application and notified the applicant of this fact by letter dated February 11, 1992. The completed PMA was then submitted and renumbered PMA 970003 on January 27, 1997, which is considered to be the PMA initially submitted date.

3. *The date the application was approved*: July 16, 1997. FDA has verified the applicant's claim that PMA 970003 was approved on July 16, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,761 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 11, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 10, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies