Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report.''

One comment suggested adding a box to the 3500A form to require drug manufacturers to state the date the report was forwarded to FDA. This is currently required for medical device reporting, but not for drugs and biologics. However, all manufacturers must report the date received by the manufacturer on form 3500A, section G4. Many large manufacturers have data bases that contain the date the information was received and the date the report was sent to FDA. As a surrogate, these two dates can be compared to see if the company is fulfilling its requirements under the regulations. The agency can use its regulatory discretion in deciding whether or not action is warranted in the case of delayed reports. What is of greater concern is the failure to report and that cannot be detected by adding this information to the form. Given that the goal is for both pharmaceutical and medical device industries to submit the majority of mandatory reports electronically, it would present a financial burden to revamp systems to accommodate a paper form that will be virtually obsolete in the future.

One comment suggested a ''tick box for a 30-day report,'' for form 3500A. At this time there is no requirement for a 30-day report.

As both the 3500 instructions and 3500A instructions can be updated periodically based on questions/comments from stakeholders and statutory/regulatory changes, changing the forms themselves is not seen as necessary at this point.

At such time it is decided to repropose revisions, FDA will consult all interested parties for input into the design.

FDA estimates the burden 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
CBER/CDER[2]					
Form 3500	16,198	1	16,198	0.5	8,099
Form 3500A (310.305, 314.80, 314.98, and 600.80)	600	455.2	273,109	1	273,109
CDRH[3]					
Form 3500	2,650	1	2,650	0.5	1,325
Form 3500A (part 803)	2,046	24	49,305	1	49,305
CFSAN[4]					
Form 3500	550	1	550	0.5	275
Form 3500A	0	0	0	1	0
No mandatory requirements					
Total Hours					332,113
Form 3500					9,699
Form 3500A					322,414

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research.
[3] Center for Devices and Radiological Health.
[4] Center for Food Safety and Applied Nutrition.
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 calendar year 1999 reports and respondents.

As more medical products are approved by the 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 voluntary reports will be submitted. Conversely, with the current plans for increasing electronic submissions it is expected that the number of mandatory reports will decrease.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29324 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1435]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by December 18, 2000.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514—(OMB Control No. 0910–0356)—Extension

Description: Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) on October 9, 1996. As directed by the ADAA, FDA published a final rule July 28, 1999 (64 FR 40746), amending part 514 (21 CFR part 514) to further define substantial evidence in a manner that encourages the submission of new animal drug applications (NADA's), supplemental NADA's and encourages dose range labeling. Substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended uses under the conditions of use suggested in its proposed labeling. It is defined as evidence consisting of one or more adequate and well-controlled studies, such as a study in a target species, study in laboratory animals, field study, bioequivalence study, or an in vitro study, on the basis of which it could fairly and reasonably be concluded by qualified experts that the new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. The provisions of § 514.4(a) provide the agency with greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. The agency believes this regulation over time, will reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs, will eliminate the need for an adequate and well-controlled dose titration study, and may, in limited instances, reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug.

Description of Respondents: Respondents to this collection of information are persons and businesses, including small businesses. In the **Federal Register** of August 16, 2000 (65 FR 49989), the FDA published a 60-day notice concerning the proposed extension of this collection of information and requested comments. No comments were received on the estimated annual reporting burden. We therefore believe the total burden estimate of 544,036 hours for the annual reporting and recordkeeping burden should remain unchanged.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
514.4(a)	190	4.5	860	632.6	544,036

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

The estimated annual reporting burden is based on consultation by the Center for Veterinary Medicine with several of the major research and development firms that conduct the majority of studies submitted to establish substantial evidence of effectiveness of new animal drugs and agency records.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29325 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Consumer Roundtable; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following meeting: Consumer roundtable to discuss consumer protection priorities for the agency. The roundtable will provide an opportunity for FDA to engage in an open dialogue with individual consumer stakeholders on a variety of regulatory and consumer oriented issues. The roundtable is part of the agency's ongoing consultation with stakeholders.

Date and Time: The meeting will be held on December 13, 2000, 9 a.m. to 4 p.m.

Location: The meeting will be held at the Penthouse Conference Room, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC.

Contact: Karen R. Mahoney, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4393, FAX 301–827–2866, e-mail: *kmahoney@oc.fda.gov*.

Registration: Preregistration is required as space is limited. Send registration information (including name, title, organization name, address, telephone, fax number, and e-mail) to the contact person by December 6, 2000.

If you need special accommodations due to a disability, please contact Karen R. Mahoney (address above) at least 7 days in advance.

Background information on this meeting will be available on the FDA Internet site at *http://www.fda.gov/opacom/hpmeetings.html*.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29424 Filed 10–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.