

any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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 before submitting the collection to OMB

for approval. To comply with this requirement, FDA is publishing a notice of the proposed collection of information set forth in this document.

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.

Title: How to Use E-mail to Submit a Protocol

Description: CVM may review protocols for safety and effectiveness studies of new animal drugs submitted by sponsors. The review of protocols facilitates the drug review and approval processes.

Protocols for nonclinical laboratory studies (safety studies) are required under 21 CFR 58.120. Protocols for effectiveness studies are required under § 514.117(b). The burden hours associated with preparing the protocols and appendices were reported and approved under OMB control number 0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for adequate and well-controlled effectiveness studies. In this guidance document CVM is giving sponsors the option to submit a protocol as an attachment via the Internet.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3536	190	0.52	100	0.20	20

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

The burden estimate was calculated as the time it takes to submit the protocol which consists of filling out the form and pressing the “insertsubmission” button, adding the password and pressing the “mail to” button, since the burden for protocol is already estimated under OMB control number 0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for efficacy studies. The number of approved sponsors is 190, we routinely receive about 100 protocols a year, and the 12 minutes (.2 *60 minutes/hour) is an estimate based on talking to participating sponsors and our testing the use of the form.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Written comments concerning the information collection requirements must be received by the Dockets

Management Branch by June 3, 2003. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments on the guidance document may be submitted on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on the Internet site, select “03D–0057 How to Use E-mail to Submit a Protocol” and follow the directions. A copy of this document may be obtained on the Internet at <http://www.fda.gov/cvm>.

Dated: March 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0094]

Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual guidance document agenda. FDA committed to publishing, on an annual basis, a list of possible topics for future guidance document development or revision during the next year, and seeking public comment on additional ideas for new guidance documents or revisions of existing ones. This commitment was made in FDA’s September 2000 good guidance practices (GGPs) final rule, which sets forth the agency’s policies and procedures for the development, issuance, and use of guidance documents. This list is intended to seek public comment on possible topics for guidance documents and possible revisions to existing guidance.