materials for applications for approval of new drugs when human efficacy studies are not ethical or feasible. (The information collection burden estimate for § 314.640 is included in table 1 of this document under the estimates for § 314.81(b)(3)(i)).

Respondents to this collection of information are all persons who submit an application or abbreviated application or an amendment or supplement to FDA under part 314 to obtain approval of a new drug, and any person who owns an approved application or abbreviated application.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section [Form Number]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
314.50(a), (b), (c), (d), (e), (f), and (k)	85	1.41	120	1,917	230,040
314.50(i) and 314.94(a)(12)	96	9.61	923	2	1,846
314.50(j)	71	4.02	286	2	572
314.52 and 314.95	71	3.66	260	16	4,160
314.60	305	15.05	4,590	80	367,200
314.65	13	1.08	14	2	28
314.70 and 314.71	281	9.30	2,613	150	391,950
314.72	69	3.40	235	2	470
314.81(b)(1) [3331]	114	2.68	306	8	2,448
314.81(b)(2) [2252]	724	11.15	8,073	40	322,920
314.81(b)(3)(i) [2253]	390	61.39	23,942	2	47,884
314.94(a)(1) through (a)(11) and (d)	110	7.21	793	480	380,640
314.96	300	28	8,400	80	672,000
314.97	215	20.66	4,442	80	355,360
314.99(a)	40	2.02	81	2	162
314.101(a)	1	1	1	.50	.50
314.107(c) 314.107(e) 314.107(f)	56 25 56	4.1 3.92 4.1	230 98 230	.50 .50 .50	115 49 115
314.110(a)(5)	45	1.15	52	.50	26
314.120(a)(5)	10	1.20	12	.50	6
314.420	487	1.98	964	61	58,804
Total					2,836,795.5

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

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: December 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–25593 Filed 1–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0367]

Draft Guidance for Industry on Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 8, 2008, the comment period for the draft guidance for industry entitled ''Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval,'' published in the **Federal Register** of October 15, 2007 (72 FR 58312). The draft guidance informed industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and asked sponsors to amend ongoing or completed studies accordingly. FDA is taking this action in response to a request for an extension of the comment period to allow interested persons additional time to review the draft guidance and submit comments.

DATES: Submit written or electronic comments by February 8, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave.,Bldg. 22, rm. 6412, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 15, 2007 (72 FR 58312), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval.'' The purpose of the guidance is to inform industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and to ask sponsors to amend ongoing or completed studies accordingly. The guidance is in response to a number of public discussions in recent years regarding the use of active-controlled studies designed to show noninferiority as a basis for approval of antibacterial drug products. Some of these discussions have focused on specific diseases such as acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. These public discussions have contributed to FDA's evolving understanding of the science of clinical trials and, in particular, the appropriate role of active-controlled studies designed to show noninferiority in the development of antibacterial drug products.

The draft guidance recommends that sponsors provide justification for the treatment effect size and the proposed noninferiority margin for all antibacterial development programs for which approval will rely on noninferiority studies. The initial comment period for this guidance closed on December 14, 2007.

II. Reopening of Comment Period

On November 13, 2007, the Pharmaceutical Research and Manufacturers of America requested an extension beyond the December 14, 2007, deadline for the submission of comments. FDA recognizes the effect this guidance may have on the development of new antimicrobial products and that additional time may be needed for comment. Therefore, FDA has decided to reopen the comment period on the draft guidance until February 8, 2008, to allow the public more time to review and comment on its contents.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm*or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–25601 Filed 1–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0489]

Request for Comments on the Science and Technology Report; Establishment of Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: On March 31, 2006, the Food and Drug Administration (FDA) charged the Science Board to evaluate FDA's science-based capacities to meet current and future public health challenges. The Science Board established a subcommittee on science and technology to perform the review and draft a report of findings and preliminary recommendations. The subcommittee report was presented and discussed at the December 3, 2007, Science Board Advisory Committee meeting, at which time the Science Board decided to obtain comments from the public on the subcommittee report. FDA is soliciting public comment on the subcommittee report on behalf of the Science Board.

DATES: To be considered, written or electronic comments on the subcommittee report must be received on or before February 4, 2008. All comments received while the docket is open will be forwarded to the Science Board for their review.

ADDRESSES: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select Docket No. 2007N–0489, ''FDA Report on Science and Technology'' and follow prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of