TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.23(a) and (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	.50	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40.00	88,320
203.31(d)(4)	442	1	442	24.00	10,608
203.31(e)	2,208	1	2,208	1.00	2,208
203.34	2,208	1	2,208	40.00	88,320
203.37(a)	25	1	25	18.00	450
203.37(b)	200	1	200	18.00	3,600
203.39(d)	65	1	65	1.00	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8.00	25,768
203.39(g)	3,221	1	3,221	8.00	25,768
203.50(a)	0	0	0	0	0
203.50(b)	0	0	0	0	0
203.50(d)	0	0	0	0	0
Total Recordkeeping Burden Hours					409,409

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

In the **Federal Register** of March 16, 2006 (71 FR 13599), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: May 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8569 Filed 6–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0215]

Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Valid or Will Not Be Infringed

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 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment, or a supplement.

DATES: Submit written or electronic comments on the collection of information by August 1, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: 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 extension 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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated NDAs Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed (OMB Control Number 0910–0513)—Extension

FDA is requesting that OMB revise and extend approval under the PRA for the information collection contained in the final rule entitled ''Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed'' (68 FR 36676, June 18, 2003) (the June 2003 final rule).

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(1)) requires all NDA applicants to file, as part of the NDA, ''the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture[,] use, or sale of the drug.'' Section 505(c)(2) of the act imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. Under section 505(b)(1) of the act, we publish patent information after approval of an NDA application in the list entitled ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book). If patent information is submitted after NDA approval, section 505(c)(2) of the act directs us to publish the information upon its submission.

The June 2003 final rule clarified the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement. The June 2003 final rule also required persons submitting an NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using required forms (Form FDA 3542a and Form FDA 3542).

Certain sections of the June 2003 final rule regarding the application of 30-month stays on approval of certain abbreviated new drug applications (ANDAs) and certain other NDAs, known as 505(b)(2) applications, submitted under the act, were superseded by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, signed December 8, 2003. The affected sections of the regulations issued in the June 2003 final rule—under part 314 (21 CFR part 314), §§ 314.52(a)(3) and 314.95(a)(3)—were revoked by the technical amendment to the June 2003 final rule, published in the **Federal Register** of March 10, 2004 (69 FR 11309). Accordingly, FDA's request to extend approval under the PRA for the collection of information contained in the June 2003 final rule is revised to exclude the revoked sections of the regulations, §§ 314.52(a)(3) and 314.95(a)(3), and certain sections of the regulations, §§ 314.50(i)(1)(i) and 314.94(a)(12), which were included in the estimated annual reporting burden to describe an information collection burden associated with the revoked sections of the regulations.

The reporting burden for submitting an NDA, an amendment, or supplement in accordance with § 314.50(a) through (f), and (k) has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910–0001, most recently until May 31, 2008 (70 FR 35099, June 16, 2005). In addition, the reporting burden associated with the previously-referenced §§ 314.50(i)(1)(i) and 314.94(a)(12), regarding patent certification requirements for 505(b)(2) applications and ANDAs also has been estimated and included within the collection of information approved by OMB under OMB control number 0910–0001. We are not re-estimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing in the final rule are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, an amendment, or a supplement contain patent information described under § 314.53.

Section 314.53 requires that an applicant submitting an NDA, an amendment, or a supplement, except as provided in § 314.53(d)(2), submit on FDA Forms 3542 and 3542a, the required patent information described in the section.

Compliance with the information collection burdens under §§ 314.50(h) and 314.53 consists of submitting with an NDA, an amendment, or a supplement (collectively referred to as ''application'') the required patent declaration(s) on Form FDA 3542a for each ''patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product'' (§ 314.53(b)). Such patents claim the drug substance (active ingredient), drug product (formulation and composition), or method of use. If a patent is issued after the application is filed with FDA but before the application is approved, the applicant must submit the required patent information on Form FDA 3542a as an amendment to the application, within 30 days of the date of issuance of the patent.

Within 30 days after the date of approval of an application, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use for listing in

the Orange Book. In addition, for patents issued after the date of approval of an application, Form FDA 3542 must be submitted within 30 days of the date of issuance of the patent.

Following publication of the June 2003 final rule, the numbers of patents submitted to FDA for listing in the Orange Book in 2004 and 2005 were 244 and 295, respectively, for an annual average of 269.5 ((244 patents + 295 patents) / 2 years = 269.5 patents / year). Because many of these individual patents are included in multiple NDA submissions, there could be multiple declarations for a single patent. From our review of submissions, we believe that approximately 14 percent of the patents submitted are included in multiple NDA submissions, and thus require multiple patent declarations. Therefore, we estimate that 38 (269.5 patents x 14 percent) patent declarations will be multiple listings, and there will be 308 (269.5 declarations + 38 declarations = 307.5 declarations) total annual patent declarations on Form FDA 3542.

As we approved 113 and 78 NDAs in 2004 and 2005, respectively, we assume there will be 96 ((113 approvals + 78 approvals) / 2 years = 95.5 approvals / year) instances where an NDA holder would be affected by the patent declaration requirements, and that each of these NDA holders would, on average, submit 3.2 (308 declarations / 96 instances = 3.2 declarations per instance) declarations on Form FDA 3542.

As we received 112 and 115 NDAs in 2004 and 2005, respectively, we assume there will be 114 ((112 applications + 115 applications) / 2 years = 113.5 applications / year) instances where an NDA holder would be affected by the patent declaration requirements. We estimate, based on a proportional increase from the number of declarations for approved NDAs, that there will be an annual total of 365 (114 instances x 3.2 declarations per instance = 365 declarations) declarations on Form FDA 3542a submitted with these applications.

The previous burden hour estimate of 1,684 hours for § 314.50 covered paragraphs (a) through (f), (k), and (h) (citing § 314.53) and FDA Forms 3542 and 3542a (see June 2003 final rule), due to the difficulty in determining what proportion of the burden hour estimate for § 314.50(a) through (f), (h), and (k), was attributable to patent declarations. Based upon information provided by regulated entities and other information, we estimate that the information collection burden associated with § 314.50(h) (citing § 314.53) and FDA Forms 3542a and 3542 will be approximately 20 hours and 5 hours per response, respectively.

Thus, the information collection burden for § 314.50(h) (citing § 314.53) and FDA Forms 3542 and 3542a will decrease from the estimate we made in the June 2003 final rule for § 314.50(a) through (f), (h), and (k), and FDA Forms 3542 and 3542a of 498,464 hours to 8,840 hours ((365 annual responses x 20 hours per response = 7,300 hours) + (308 annual responses x 5 hours per response = 1,540 hours) = 8,840 total hours).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Form FDA 3542a	114	3.2	365	20	7,300
Form FDA 3542	96	3.2	308	5	1,540
Total					8,840

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

Dated: May 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8570 Filed 6–1–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0019]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Food and Drug Administration Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

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 July 3, 2006.

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: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Draft Guidance for Industry and FDA Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

Under the Safe Medical Devices Act of 1990 (Public Law 101–629, 104 Stat. 4511), FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. This draft guidance document serves as the special control to support the reclassification from class III to class II