DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0472]

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Certifier D. Hawkins

Agency Emergency Processing Under the Office of Management and Budget Review; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the certification to accompany human drug, biological product, and device applications or submissions.

DATES: Fax written comments on the collection of information by [*insert date 3 days after date of publication in the* **Federal Register**].

ADDRESSES: 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, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title, "Certification to Accompany Drug, Biological Product, and Device Applications or Submissions." Also include the FDA docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). The emergency processing was requested in order to comply with the provisions of Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), which require this certification to be submitted to FDA beginning no later than December 26, 2007. This information will be needed immediately to implement these provisions of FDAAA, and it is essential to the agency's mission of protecting and promoting the public health. Since the statutory deadline for collecting the information is December 26, 2007, the lack of a form would result in confusion for the sponsors/applicants as the information necessary for FDA to carry out its future statutory responsibilities would not be obvious without the form. While some sponsors/applicants may submit information, it most likely would neither be complete nor provided in a systematic fashion so that it can be more easily retrieved.

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.

Certification to Accompany Drug, Biological Product, and Device Applications or Submissions

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)), will be submitted in the form of a certification with applications and submissions currently submitted to FDA under part 312 (21 CFR part 312) and 21 CFR part 314 (human drugs) approved under OMB control numbers 0910–0014 (expires May 31, 2009) and 0910–0001 (expires May 31, 2008), respectively, part 312 and 21 CFR part 601 (biological products) approved under OMB control numbers 0910–0014 and 0910–0338 (expires June 30, 2010) and 21 CFR parts 807 and 814 (devices) approved under OMB control numbers 0910–0120 (expires August 31, 2010) and 0910–0231 (expires November 30, 2010), respectively.

Title VIII of FDAAA amended the PHS Act by adding section 402(j) (42 U.S.C. 282(j)). The new provisions require additional information to be submitted to the clinical trials data bank (*ClinicalTrials.gov*) previously established by the National Institutes of Health/National Library of Medicine, including expanded information on clinical trials and information on the results of clinical trials. The provisions include new responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

One new provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 354, 360e, or 360j(m)), or under section 351 of the PHS Act (21 U.S.C. 262),

or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

The proposed collection of information is necessary to satisfy the above statutory requirement.

The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties.

Investigational New Drug Applications

FDA's Center for Drug Evaluation and Research (CDER) received 1,837 investigational new drug applications (INDs) and 24,581 new IND amendments in fiscal year (FY) 2004. CDER anticipates that IND and amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 227 new INDs and 6,689 new IND amendments in FY 2004. CBER anticipates that IND and amendment submission rates will remain at or near this level in the near future.

The estimated total number of submissions (new INDs and new submissions) subject to mandatory certification requirements under section 402(j)(5)(B) of the PHS Act is 26,418 for CDER plus 6,916 for CBER, or 33,334 submissions per year. The minutes per response is the estimated number of minutes that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to type the necessary information.

Based on its experience reviewing INDs and consideration of the previously mentioned information, FDA estimated that approximately 15.0 minutes on average would be needed per response for certifications which accompany IND applications and submissions. It is assumed that most submissions to investigational applications will reference only a few protocols with NCT numbers prior to FDA submission. It is also assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Marketing Applications/Submissions

CDER and CBER received 214 new drug applications (NDA)/biologics license applications (BLA)/resubmissions and 8,535 NDA/BLA amendments in FY 2004. CDER and CBER received 259 efficacy supplements/resubmissions to previously approved NDAs/BLAs, 2,500 manufacturing submissions, and 1,273 labeling submissions in FY 2004. CDER and CBER anticipate that new drug/biologic and efficacy supplement submission rates will remain at or near this level in the near future.

FDA's Center for Devices and Radiological Health (CDRH) received 51 new premarket approvals (PMA), 3,635 510(k) submissions, and 9 humanitarian device exemptions (HDE) or 3,695 new applications in FY 2004. CDRH

received 2,267 PMA/510(k)/HDE amendments in FY 2004. CDRH received 2,705 PMA/510(k)/HDE supplements in FY 2004. CDRH anticipates that application, amendment, and supplement rates will remain at or near this level in the near future.

The estimated total number of new submissions (new marketing applications, amendments, and supplements) subject to the mandatory certification requirements under section 402(j)(5)(B) of the PHS Act is 12,781 for CDER and CBER plus 8,667 for CDRH or 21,448 new submissions per year.

The total burden estimate includes all submissions for possible inclusion in the clinical trials data bank (results). The minutes per response is the estimated number of hours that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to type the necessary information and compile a list of relevant NCT numbers.

Based on its experience reviewing NDAs, BLAs, PMAs, HDEs, and 510(k)s, and consideration of the previously mentioned information, FDA estimated that approximately 45.0 minutes on average would be needed per response for certifications which accompany NDA, BLA, PMA, HDE, and 510(k) applications and submissions. It is assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Table 1 of this document provides an estimate of the annual reporting burden for the submission of information to satisfy the requirements of section 402(j)(5)(B) of the PHS Act.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Investigational Applications	Marketing Applications	Hours per Response	Total Hours
CDER (new application)	1,837	----	.25	459

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

	Investigational Applications	Marketing Applications	Hours per Response	Total Hours
CBER (new application)	227	----	.25	57
CDER (amendment)	24,581	----	.25	6,145
CBER (amendment)	6,689	----	.25	1,672
CDER/CBER (new application/resubmission)	----	214	.75	161
CDRH (new application)	----	3,695	.75	2,771
CDER/CBER (amendment)	----	8,535	.75	6,401
CDRH (amendment)	----	2,267	.75	1,700
CDER/CBER (efficacy supplement/resubmission)	----	259	.75	194
CDER/CBER (manufacturing supplement)	----	2,500	.75	1,875
CDER/CBER (labeling supplement)	----	1,273	.75	955
CDRH (supplement)	----	2,705	.75	2,029
TOTAL				24,419

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

We believe the estimate, 24,419 hours per year, accurately reflects the burden. We recognize that individuals or entities less familiar with FDA forms and the Clinical Trials Data Bank may require greater than 15 and 45 minutes (depending on the type of application/submission) per response.

Dated: DEC 0 6 2007

December 6, 2007.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

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Dawn P. Hawkins