Guidance for Industry on "How to Submit a Protocol Without Data in Electronic Format to the Center for Veterinary Medicine"—21 CFR 58.120 and 514.117(b) (OMB Control Number 0910–0524—Extension)

Protocols for nonclinical laboratory studies (safety studies), are required under 21 CFR 58.120 for approval of new animal drugs. Protocols for adequate and well-controlled effectiveness studies are required under 21 CFR 514.117(b). Upon request by the animal drug sponsors, the Center for Veterinary Medicine (CVM) reviews protocols for safety and effectiveness studies. CVM and the sponsor consider this to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application. The establishment of a process for acceptance of the electronic submission of protocols for studies conducted by sponsors in support of new animal drug applications is part of CVM's ongoing initiative to provide a method for paperless submissions. Sponsors may submit protocols to CVM in paper format. CVM's guidance on how to submit a study protocol permits sponsors to submit a protocol without data as an e-mail attachment via the Internet. Further, this guidance also electronically implements provisions of the Government Paperwork Elimination Act (GPEA). The GPEA required Federal agencies, by October 21, 2003, to provide the following: (1) The option of electronic maintenance, submission, or disclosure of information, if practicable, as a substitution for paper and (2) the use and acceptance of electronic signatures, where applicable. FDA Form 3536 is used to facilitate the use of electronic submission of protocols. This collection of information is for the benefit of animal drug sponsors, giving them the flexibility to submit data for review via the Internet.

The likely respondents are sponsors of new animal drug applications.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/FDA Form 3536	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
514.117(b) and 58.120	40	1.8	72	.20	14.4

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Electronic submissions received between January 1, 2008, and December 31, 2008.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total annual responses is based on a review of the actual number of such submissions made between July 1, 2005, and June 30, 2006, (72 x .20 hours per response = 14.4 total hours).

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0062]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exception From General Requirements for Informed Consent

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 a new exception from the general requirements for informed consent to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances.

DATES: Submit written or electronic comments on the collection of information by April 19, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

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.

Medical Devices; Exception From General Requirements for Informed Consent—21 CFR 50.23 (OMB Control Number 0910–0586)—Extension

In the **Federal Register** of June 7, 2006 (71 FR 32827), FDA issued an interim final rule (hereinafter referred to as the June 7, 2006, interim final rule) to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The agency took this action because it was concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

Section 50.23(e)(1) (21 CFR 50.23(e)(1)) provides an exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device. This exception will apply to those situations in which the in vitro investigational diagnostic device is used to prepare for and respond to a chemical, biological, radiological, or nuclear terrorism event or other public health emergency, if the investigator and an independent licensed physician make the determination and later certify in writing that: (1) There is a life-threatening situation necessitating the use of the investigational device; (2) obtaining informed consent from the subject is not feasible because there was no way to predict the need to use the investigational device when the specimen was collected and there is not sufficient time to obtain consent from the subject or the subject's legally authorized representative; and (3) no satisfactory alternative device is available. Under the June 7, 2006, interim final rule these determinations are made before the device is used, and the written certifications are made within 5 working days after the use of the device. If use of the device is necessary to preserve the life of the subject and there is not sufficient time to obtain the determination of the independent licensed physician in advance of using the investigational device, § 50.23(e)(2) provides that the certifications must be made within 5 working days of use of the device. In either case, the certifications are submitted to the Institutional Review Board (IRB) within 5 working days of the use of the device.

Section 50.23(e)(4) provides that an investigator must disclose the investigational status of the device and what is known about the performance characteristics of the device at the time test results are reported to the subject's health care provider and public health authorities, as applicable. Under the June 7, 2006, interim final rule, the investigator provides the IRB with the information required by § 50.25 (21 CFR 50.25) (except for the information described in § 50.25(a)(8)) and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative.

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

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

21 CFR Section	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per response	Total hours
50.23(e)(1)(2)	150	3	450	2	900
50.23(e)(4)	150	3	450	1	450
Total					1350

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

From its knowledge of the industry, FDA estimates that there are approximately 150 laboratories that could perform testing that uses investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents. FDA estimates that in the United States each year there are approximately 450 naturally occurring cases of diseases or conditions that are identified in Centers for Disease Controls's list of category "A" biological threat agents. The number of cases that would result from a terrorist event or other public health emergency is uncertain. Based on its knowledge of similar types of submissions, FDA estimates that it will take about 2 hours to prepare each certification.

Based on its knowledge of similar types of submissions, FDA estimates that it will take about 1 hour to prepare a report disclosing the investigational status of the in vitro diagnostic device and what is known about the performance characteristics of the device and submit it to the health care provider and, where appropriate, to public health authorities.

This interim final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 50.25 have been approved under 0910–0130.

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0496]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Product Standard on Flavored Cigarettes

AGENCY: Food and Drug Administration, HHS.