DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2549]

Agency Information Collection Activities: Proposed Collection; Comment Request; Cosmetic Product Voluntary Reporting Program; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 9, 1999 (64 FR 43188). The document announced that a proposed collection of information had been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The document was published with an incorrect docket number. This document corrects that error.

DATES: August 25, 1999.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In the FR Doc. 99–20359, appearing on page 43188 in the **Federal Register** of Monday, August 9, 1999, the following correction is made:

On page 43188, in the first column, ''[Docket No. 99N–0185]'' is corrected to read ''[Docket No. 99N–2549]''.

Dated: August 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–21967 Filed 8–24–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0297]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Draft Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 24, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Title: Draft Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

Description: FDA is issuing a draft guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biological Evaluation and Research (CBER) that cannot be resolved at the division level. The draft guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The draft guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding internal agency review of decisions (§ 10.75 (21 CFR 10.75)) and dispute resolution during the investigational new drug (IND) process (21 CFR 312.48) and the new drug application (NDA)/abbreviated new drug application (ANDA) process (21 CFR 314.103). In addition, the draft guidance provides information on how the agency will interpret and apply the specific Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102–571) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the agency, CDER, and CBER. All agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in parts 312 (OMB Control No. 0910–0001), 314 (OMB Control No. 0910–0014), and part 601 (21 CFR part 601) (OMB Control No. 0910–0315), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requester in the appeal would facilitate timely resolution of the dispute. The draft guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§ § 312.23(11)(d), 314.50, 314.94, and 601.2) state that information provided to the agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under IND's, and Form FDA 356h must accompany submissions under NDA's, ANDA's, and BLA's. Both forms have valid OMB control numbers as follows: Form FDA 1571, OMB Control No. 0910–0014, expires December 31, 1999; and Form FDA 356h, OMB Control No. 0910–0338, expires April 30, 2000.

In the draft guidance, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate

tracking data bases. Use of the information in the agency's tracking data bases enables the appropriate agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the draft guidance recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the Center may quickly and efficiently respond to the request:

- A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (i.e., scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome;
- A statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last agency official that attempted to formally resolve the matter;
- A list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and
- A statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the agency suggests submitting with a formal request for dispute resolution consists of : (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) documents previously submitted to FDA under an OMB approved collection of information (see previous discussion).

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the agency under the act or section 351 of the Public Health Service Act who requests formal resolution of a scientific or procedural dispute.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for requests for dispute resolution. In fiscal year (FY) 1998, 39 sponsors and applicants (respondents) submitted requests for formal dispute resolution to CDER and 12 respondents submitted requests for formal dispute resolution to CBER . Although the procedures for requesting formal dispute resolution that are set forth in the draft guidance were not in place in FY 1998, FDA estimates that the number of respondents who would submit requests for dispute resolution under the guidance would remain the same. The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. In FY 1998, CDER received approximately 49 requests and CBER received approximately 15 requests. The agency estimates that the total annual responses will remain the same, averaging to 1.26 responses per respondent. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this draft guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 512 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

On Friday, March 9, 1999, FDA invited comments on this analysis of information collection burdens. FDA received one comment regarding the agency's estimate of the paperwork burden. The comment stated that FDA's estimate is a relatively accurate accounting of time used in administrative preparation of information for requests for dispute resolution of procedural matters. The comment stated that FDA underestimated the time required for creative writing and editing tasks associated with preparation of paperwork to resolve disputes of a scientific or technical nature.

The agency's estimates are based in part on the expectation that respondents will have already compiled for submission to the agency most of the data and information that is described in the guidance document. The agency anticipates that respondents will have submitted the information as part of the underlying product application. Therefore, the bulk of the paperwork burden is related to administrative tasks (i.e., gathering and copying brief statements describing the issue from the perspective of the person with the dispute and brief statements describing the history of the matter).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Results for Formal Dispute Resolution	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	39	1.26	49	8	392
CBER	12	1.25	15	8	120
Total					512

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

Dated: August 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–21965 Filed 8–24–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2211]

Medical Devices; Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA.'' This draft guidance is intended to identify the elements for an investigational device exemption/premarket approval application (IDE/PMA) for any electro-optical sensor in vivo device for the detection of cervical cancer or its precursors. This draft guidance covers electro-optical devices applied to a woman's cervix in an in vivo setting that give a relatively instantaneous reading of test results for the purposes of detection of cervical cancer and its precursors. Many of these systems use complex signal discrimination algorithms and/or neural networks to differentiate abnormal from normal tissue. These new technologies, depending upon design and study results, may ultimately complement, as an adjunct, or replace the PAP smear, or it may serve to improve the results of colposcopy or biopsy. This draft guidance is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by November 23, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled, ''Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA.'' This draft guidance is intended to identify the elements for an IDE and/or a PMA application for electro-optical sensors that are used in a clinical in vivo setting for the detection of cervical cancer or its precursors. This draft guidance is the result of several preliminary interactions between FDA and developers of this type of device, as well as input from experts at a meeting of FDA's advisory committee, the Obstetrics and Gynecology Devices Panel, on July 14 and 15, 1997. The draft guidance covers various types of hand-held probes that employ electro-optical sensor technology to optically interrogate the cervix uteri for cancer and its precursors. Many of these systems use complex signal discrimination algorithms and/or neural networks to differentiate abnormal from normal tissue; and, generally, these sensors provide a relatively instantaneous riding of test results. The new technology covered by this guidance document, depending upon design and study results, may complement, as an adjunct, or replace the PAP smear, or it may serve to improve the results of colposcopy or biopsy. These in vivo detection devices apply several different optical phenomena, including autofluorescence and Raman spectroscopy. Some may include bioelectrical phenomena.

This draft guidance document represents the agency's current thinking on the appropriate content of IDE/PMA applications for in vivo devices for the detection of cervical cancer and its precursors. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive ''Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (266) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the ''Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA'' will be available at ''http://www.fda.gov/scripts/cdrh/ctdocs/cfggp/results.cfm''.

III. Comments

Interested persons may, on or before November 23, 1999, submit to the Dockets Management Branch (address