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Medical Devices; Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA.'' This draft guidance is intended to identify the elements for an investigational device exemption/premarket approval application (IDE/PMA) for any electro-optical sensor in vivo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 This draft guidance covers electro-optical devices applied to a woman's cervix in an in vivo setting that give a relatively instantaneous reading of test results for the purposes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 This draft guidance is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by November 23, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA'' to the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

above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 28, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2638]

Use of Medicated Feeds for Minor Species; Draft Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled ''Use of Medicated Feeds for Minor Species.'' The purpose of the draft CPG is to provide guidance to the field concerning the agency's exercise of regulatory discretion with regard to the extra-label use of medicated feeds for minor species.

DATES: Written comments on the draft CPG may be submitted by November 23, 1999.

ADDRESSES: Submit written requests for single copies of the draft CPG entitled ''Use of Medicated Feed for Minor Species'' to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judy A. Gushee, Center for Veterinary Medicine (HFV–232), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0150, e-mail ''jgushee@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

Prior to 1994, the Federal Food, Drug, and Cosmetic Act (the act) did not permit extra-label use of animal drugs, but FDA exercised regulatory discretion regarding extra-label use of animal drugs provided certain criteria were met. These criteria were published in CPG 7125.06 and were largely incorporated into the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). AMDUCA amended the act to permit extra-label uses under certain conditions. The AMDUCA regulations are codified in 21 CFR part 530. AMDUCA did not permit extra-label use of medicated feeds. However, there are some minor species that cannot be practically medicated in any other way other than through the use of medicated feeds. Furthermore, minor species such as fish and game birds have very few drugs approved for their use. In such situations, a veterinarian may determine that extra-label use of medicated feeds approved for use in other species can prevent suffering and death in these minor species. Before the implementation of AMDUCA, the agency occasionally exercised regulatory discretion for extra-label use of medicated feeds for minor species based on a medical need as long as the medicated feeds were formulated and labeled in accordance with their approved application. Because AMDUCA did not permit extra-label use of medicated feeds, FDA is providing this guidance to our field personnel when such extra-label use is encountered.

This level 1 draft guidance document is being issued consistent with FDA's good guidance practices (62 FR 9061, February 27, 1997). This draft CPG represents the agency's current thinking with regard to the extra-label use of medicated feeds for minor species. It does not 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 requirements of the applicable statute, regulations, or both.

II. Request for Comments

Interested persons may, on or before November 23, 1999, submit to the Dockets Management Branch (address above) written comments on the draft CPG entitled ''Use of Medicated Feeds for Minor Species.'' Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft CPG and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. The agency will review all comments, but in issuing a final CPG, need not specifically address every comment. The agency will make changes to the draft CPG in response to comments, as appropriate.

III. Electronic Access

Copies of the draft CPG may also be downloaded to a personal computer with access to the World Wide Web (www). The Office of Regulatory Affairs (ORA) and CVM home pages include the draft CPG and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cvm'', respectively. The draft CPG will be available on the compliance references or compliance information pages for ORA and CVM, respectively.

Dated: August 18, 1999.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–30]

Agency Information Collection Activities: Proposed Collection; Comment Request; Notice

AGENCY: Health Care Financing Administration, HHS.

ACTION: Notice.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.