The priority score will be based on the scientific/technical review criteria in section V.C of this document. In addition, the reviewers may advise the program staff concerning the appropriateness of the proposal to the goals of the OPD Grant Program described in section I (Program Research Goals) of this document.

D. Award Criteria

Resources for this program are limited. Therefore, should two or more applications be received and approved by FDA which propose duplicative or very similar studies, FDA will support only the study with the best score.

VI. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98) or the original and two copies of the PHS 5161 (Rev. 6/99) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura C. Stephanos (address above). State and local governments may choose to use the PHS 398 application form in lieu of the PHS 5161. The application receipt dates are October 16, 2000, and March 15, 2001. No supplemental or addendum material will be accepted after the receipt date. Evidence of final IRB approval will be accepted for the file after the receipt date.

The outside of the mailing package and item two of the application face page should be labeled, ''Response to RFA FDA OPD–2001.''

If an application for the same study was submitted in response to a previous RFA (RFA FDA–OPD–2000) but has not yet been acted upon, a submission in response to this RFA will be considered a request to withdraw the previous application. Resubmissions are treated as new applications; therefore, the applicant may wish to address the issues presented in the summary statements from the previous review.

VII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt dates.

Applications will be considered received on time if sent or mailed on or before the receipt dates as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

Do not send applications to the Center for Scientific Research (CSR), NIH. Any application that is sent to the NIH, that is then forwarded to FDA and received after the applicable due date, will be deemed unresponsive and returned to the applicant. Instructions for completing the application forms can be found on the NIH home page on the Internet (address http://www.nih.gov/grants/funding/phs398/phs398.html; the forms can be found at http://www.nih.gov/grants/funding/phs398/forms__toc.html). However, as noted above, applications are not to be mailed to the NIH. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by the NIH on its applications). Applications must be submitted via mail delivery as stated above. FDA is unable to receive applications via the Internet.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to the CSR, NIH. Applications from State and Local Governments may be submitted on Form PHS 5161 (Rev. 6/99) or Form PHS 398 (Rev. 4/98).

The face page of the application should reflect the request for applications number RFA–FDA–OPD–2001. The title of the proposed study should include the name of the product and the disease/disorder to be studied along with the IND/IDE number. The format for all subsequent pages of the application should be single-spaced and single-side.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the DHHS or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: July 31, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19991 Filed 8–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1343]

Medical Devices; Exemption From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a notice announcing that it has received a petition requesting exemption from the premarket notification requirements for the barium enema retention catheter with or without bag class II device (special controls). FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by September 7, 2000.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act)

(21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513 (c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to published in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify 159 when prompted for the document shelf number.

III. Petition

FDA received the following petition requesting an exemption from premarket notification for class II devices: E–Z–EM, Inc, Barium enema retention catheter with or without bag (21 CFR 876.5980).

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this petition by September 7, 2000. 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. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 2000.

Linda S. Kahan,

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

[FR Doc. 00–19951 Filed 8–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA920–1310–EI: CACA 28211]

California: Notice of Proposed Reinstatement of Terminated Oil and Gas Lease

Under the provisions of Public law 97–451, a petition for reinstatement of oil and gas lease CACA 28211 for lands in Kern County, California, was timely filed and was accompanied by all the required rentals and royalties accruing from November 1, 1999, the date of termination.

No valid lease has been issued affecting the lands. The lessee has agreed to amend lease terms for rentals and royalties at the rate of $5.00 per acre, or fraction thereof, per year and 16⅔ percent, respectively. The lessee has paid the required $500 administrative fee and $125 to reimburse the Department for the cost of this **Federal Register** notice.

The lessee has met all the requirements for reinstatement of the lease as set out in sections 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease CACA 28211 effective November 1, 1999, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

FOR FURTHER INFORMATION CONTACT: Bonnie Edgerly, Land Law Examiner, California State Office (916) 978–4370.

Dated: July 27, 2000.

Modesto Tamondong,

Acting Chief, Branch of Energy, Mineral Science, and Adjudication.

[FR Doc. 00–19957 Filed 8–7–00; 8:45 am]

BILLING CODE 4310–40–M