exclusively for fluids with low potential risks, such as enteral feeding or anti-infectives, were subject to tracking. The agency has reevaluated the types of infusion pumps subject to tracking and the best way to describe them in the guidance document. The revised guidance explains that tracking is required only for electromechanical infusion pumps that are used outside a user facility. This was the agency's position in 1993 when tracking was originally implemented (58 FR 43442 at 43449). The phrase ''electromechanical only'' will be used to describe the pumps rather than a reference to the classification regulation. FDA believes this will clarify the guidance because the terms used in the classification language for infusion pumps may include types that do not require tracking.

Finally, the agency added abdominal aortic aneurysm stent grafts to the devices that must be tracked. The agency issued tracking orders for these devices on September 28, 1999, which were effective immediately. FDA determined that these devices meet the statutory tracking criteria under section 519(e) of the act because failure of the device would be reasonably likely to have serious adverse health effects. The agency may add or remove devices from the list of tracked devices as a result of its review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance, or other information.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical device tracking requirements, as amended by FDAMA. 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 guidance document is issued as a Level 2 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on Medical Device Tracking'' 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 (169) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Guidance on Medical Device Tracking,'' 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. ''Guidance on Medical Device Tracking'' will be available at http://www.fda.gov/cdrh/ochome.html.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance.

Dated: January 9, 2000.

Linda S. Kahan,

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

[FR Doc. 00–1542 Filed 1–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5297]

Medical Devices; Guidance Document for Premarket Notification Submissions for the Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance Document for Premarket Notification Submissions for the Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.'' This guidance will serve as a special control for nitric oxide delivery apparatus; nitric oxide analyzer; and nitrogen dioxide analyzer. FDA's Center for Devices and Radiological Health (CDRH) believes that this guidance is necessary to provide reasonable assurance of the safety and effectiveness of these devices. The guidance document includes material specific for the devices, consensus standards for electrical safety, electromagnetic compatibility, software and hardware documentation, and resistance to environmental effects.

DATES: Written comments concerning this guidance document must be received by April 24, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document. Submit written requests for single copies of the guidance document entitled ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer'' 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. By April 24, 2000, written comments concerning this guidance document must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. After April 24, 2000, comments must be submitted to the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Michael G. Bazaral, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION:

I. Background

On January 11, 2000, FDA issued an order to Datex-Ohmeda, Inc., under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) classifying the nitric oxide administration apparatus, the nitric oxide gas analyzer, and the nitric dioxide analyzer into class II (special controls). This guidance document is intended to serve as the special control for these devices.

FDA is making this guidance document effective immediately

because these devices are necessary for the administration of a drug that provides a significant public health benefit. The drug, which was approved by FDA on December 23, 1999, is used for the treatment of neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The drug improves oxygenation and reduces the need for extracorporeal membrane oxygenation.

The guidance document is intended to set forth the controls and testing that FDA believes ensure the safety and effectiveness of the nitric oxide administration apparatus, nitric oxide gas analyzer, and nitrogen dioxide gas analyzer. It also intends to provide comprehensive directions to enable a manufacturer to submit a 510(k) premarket notification demonstrating substantial equivalence for any or all three device types.

The guidance document identifies the risks associated with these types of devices and contains information that will help manufacturers address those risks. The guidance outlines the controls that should be incorporated in the devices for controlling risks, testing that should be completed for each device, and suggested methods for developing preclinical criteria. Other elements of the guidance document include: (1) General device description; (2) specific description of the information to support applications for each device; and (3) general considerations for each device, such as software and hardware testing.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the premarket notification submissions for the nitric oxide delivery apparatus, nitric oxide analyzer, and nitrogen dioxide analyzer. 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 guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer'' 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 (1157) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer,'' 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 ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer'' will be available at http://www.fda.gov/cdrh/ggpmain.html.

IV. Comments

Interested persons may, on or before April 24, 2000, submit to the Dockets Management Branch (address above) written comments regarding this immediately in effect guidance document. 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2000.

Linda S. Kahan,

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

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BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0298]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

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.

Type of Information Collection Request: New; *Title of Information Collection:* Evaluation of New Medicare Members of Medicare+Choice Plans; *Form No.:* HCFA–R–0298 (OMB# 0938-New); *Use:* The objective of this survey is to understand the special information needs of new Medicare members, their sources of information, their preferred distribution channels, their understanding of the traditional Medicare program and their understanding of their particular +Choice plan, and the impact National Medicare Education Program activities may have on new members' decisions to choose a +Choice plan or change their plan; *Frequency:* On occasion; *Affected Public:* Individuals; *Number of Respondents:* 3000; *Total Annual Responses:* 3000; *Total Annual Hours:* 1212.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.