

FDA has based these estimates on conversations with industry and trade association representatives and from internal FDA experience and estimates.

The total number of medical device manufacturers regulated by FDA is estimated to be 70,000. Because most of the medical devices which might be needed in a terrorist attack are available through regular commercial channels, FDA focused this collection of information on the 250 manufacturers who manufacture 17 medical devices. Therefore, FDA estimates that approximately 150 manufacturers would be contacted in a 1-year period. It is also estimated from FDA experience that the survey will take approximately 20 to 30 minutes to complete over the telephone.

Dated: March 7, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03N-0075]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices

**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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for administrative detention and banned medical devices.

**DATES:** Submit written and electronic comments on the collection of information by May 16, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit

written comments on the collection of information to the Dockets Management Branch (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:** Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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: (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.

#### Administrative Detention and Banned Medical Devices (OMB Control Number 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 334(g)), to detain during establishment inspections devices that are believed to be adulterated or misbranded. FDA issued a final rule that published in the

**Federal Register** on March 9, 1979 (44 FR 13234 at 13239) on administrative detention procedures, which includes, among other things, certain reporting requirements § 800.55(g) and (k) (21 CFR 800.55(g) and (k)) and recordkeeping requirements. Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, as well as records of distribution of the detained devices. These recordkeeping requirements for administrative detentions allow FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. The final rule for banned devices that published in the **Federal Register** of May 18, 1979 (44 FR 29221) contained certain reporting requirements §§ 895.21(d) and 895.22(a) (21 CFR 895.21(d) and 895.22(a)). Section 895.21(d) states that if the Commissioner of Food and Drugs (the Commissioner) decides to initiate a proceeding to make a device a banned device, a notice of proposed rulemaking will be published in the **Federal Register**, and this document will contain the finding that the device presents a substantial deception or an unreasonable and substantial risk of illness or injury. The document will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling or change of labeling, or change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

Respondents to this collection of information are those manufacturers,

distributors, or importers whose products FDA seeks to detain or ban. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section       | No. of Respondents | Annual Frequency per Response | Total Annual Records | Hours per Response | Total Hours |
|----------------------|--------------------|-------------------------------|----------------------|--------------------|-------------|
| 800.55(g)            | 1                  | 1                             | 1                    | 25                 | 25          |
| 895.21(d) and 895.22 | 26                 | 1                             | 26                   | 16                 | 416         |
| Total                |                    |                               |                      |                    | 441         |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per | Total Annual Records | Hours per Recordkeeper | Total Hours |
|----------------|----------------------|----------------------|----------------------|------------------------|-------------|
| 800.55(k)      | 1                    | 1                    | 1                    | 20                     | 20          |
| Total          |                      |                      |                      |                        | 20          |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Over the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. Historically, the Center for Devices and Radiological Health has had very few or no annual responses for this information collection and normally reports one response per year.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the three firms whose devices had been detained.

Dated: March 7, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03-6230 Filed 3-14-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0319]

#### Agency Information Collection Activities; Announcement of OMB Approval; Blood Establishment Registration and Product Listing, Form FDA 2830

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Blood Establishment Registration and

Product Listing, Form FDA 2830" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

#### FOR FURTHER INFORMATION CONTACT:

JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 19, 2002 (67 FR 69747), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0052. The approval expires on February 28, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: March 10, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03-6231 Filed 3-14-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98E-0849]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; VITREON; Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its determination regarding the regulatory review period for purposes of patent extension for VITREON that appeared in the **Federal Register** of December 17, 1998 (63 FR 69633). FDA is amending the document because the agency agrees with the information provided in a request from the applicant for revision of the regulatory review period.

**ADDRESSES:** Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3460.

**SUPPLEMENTARY INFORMATION:** In its application for patent term extension, the applicant claimed November 10, 1989, as the date the investigational new drug (IND) application for VITREON (IND 33,858) was initially submitted. FDA records showed that IND 33,858