

**ACTION:** Notice of Supplemental Funding Award.

**SUMMARY:** The Administration for Native Americans announces that a non-competitive grant award is being made to the InterTribal Bison Cooperative in the amount of \$140,190 for Grant #90NA7059. The project period is September 1, 1998—August 341, 2000. This supplement will augment Year 2 funding to allow for the hiring of necessary staff as well as other supports to facilitate the completion of all original objectives projected under the grant. The InterTribal Bison Cooperative is funded to provide services to forty-two member tribes, including: Marketing and sales; land base and production capacity; research and development of herd management and a collaboration with tribal colleges in developing bison curricula.

**FOR FURTHER INFORMATION CONTACT:** Lois Hodge, Grants Officer, Department of Health and Human Services, Administration for Children and Families, Office of Grants Administration, 370 L'Enfant Promenade SW., Mail Stop HHH 326F, Washington, DC 20447, telephone: 202-401-2344 or Georgeline Sparks, Program Specialist, Administration for Native Americans, DHHS./ACF/ANA, 370 L'Enfant Promenade SW., Washington, DC 20447, telephone: 202-690-6420.

**Authority:** This award will be made pursuant to Native Americans Programs Act of 1974 as amended, 42 U.S.C. 2991 B. (CFDA 93.612).

Dated: June 5, 2000.

**Gary Mounts,**

*Acting Commissioner, Administration for Native Americans.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1303]

#### Agency Information Collection Activities: Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization

**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 a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further process labeling or repacking.

**DATES:** Submit written comments on the collection of information by August 11, 2000.

**ADDRESSES:** 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 Schlosburg, 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.

#### Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control No. 0910-0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices are nonsterile, being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices.

The respondents to this collection of information are device manufacturers and contract sterilizers.

FDA estimates the reporting 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 Responses	Hours per Response	Total Hours
801.150(e)	90	20	1,800	4	7,200
Total					7,200

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

FDA's estimate of the burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement.

No burden has been estimated for the recordkeeping requirement in § 801.150(a)(2) because these records are maintained as a usual and customary part of normal business activities. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: June 5, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 00M-0811, 00M-1215, 00M-1216, 00M-0915, 99M-4619, 00M-0901, 99M-4763, 00M-0424, 00M-1073, 00M-0577, 00M-0579, 00M-0599, 00M-0445, 00M-0580, 00M-0578, 00M-0810, 00M-0809, 00M-1212]

### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a

list of premarket approval applications (PMA's) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMA's through the Internet and the agency's Dockets Management Branch.

**ADDRESSES:** Summaries of safety and effectiveness are available on the Internet at <http://www.fda.gov/cdrh/pmapage.html>. Copies of summaries of safety and effectiveness are also available by submitting a written request to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 in the **SUPPLEMENTARY INFORMATION** section of this document when submitting a written request.

**FOR FURTHER INFORMATION CONTACT:** Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's Internet home page at <http://www.fda.gov>; by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch; and by publishing in the **Federal Register** after each quarter a list of available safety and

effectiveness summaries of approved PMA's and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from January 1, 2000, through March 31, 2000. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE JANUARY 1, 2000, THROUGH MARCH 31, 2000

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970005/00M-0811	Kremer Laser Eye Center	Kremer Exciber Laser System (Serial #KEA940202)	July 30, 1998
P970055/00M-1215	Biotrin International, Ltd.	Biotrin Parvovirus IgM EIA (V619IMUS)	August 6, 1999
P970054/00M-1216	Biotrin International, Ltd.	Biotrin Parvovirus IgG EIA (V519IGUS)	August 6, 1999
P980049/00M-0915	ELA Medical, Inc.	Defender II Model 9201 Implantable Cardiovascular Defibrillator	September 15, 1999
H990003/99M-4619	American Medical Systems	Acticon™ Neosphincter	September 20, 1999