

labeling from arrhythmia-specific indications to a generic arrhythmic treatment indication. The Center for Devices and Radiological Health (CDRH) is issuing this draft guidance document to allow companies to label these products for a broader indication without submitting additional clinical information. This recommendation is based on a comprehensive search of the medical literature. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments concerning this draft guidance by March 7, 2002.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use" to the Division of Small Manufacturers, International and Consumer 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 Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Donna-Bea Tillman, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The draft guidance document recommends that manufacturers of approved conventional cardiac radiofrequency ablation catheters submit a premarket approval supplement to obtain a generic indication for creating endocardial lesions to treat arrhythmias. The draft guidance document provides evidence from the medical literature to support this broadening of indications to a generic arrhythmia treating indication.

##### **II. Significance of Guidance**

The draft guidance document, when finalized, represents the agency's current thinking on generic indications for cardiac ablation catheters. 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 and regulations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

##### **III. Electronic Access**

In order to receive "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 1382 followed by the pound sign (#). 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 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 Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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 documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

##### **IV. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance by March 7, 2002. 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 draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 28, 2001.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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#### **DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**[Docket No. FR-4630-C-35]**

##### **Announcement of Funding Awards; Indian Housing Drug Elimination Program; Fiscal Year 2001; Correction**

**AGENCY:** Office of Native American Programs, HUD.

**ACTION:** Announcement of funding awards for fiscal year 2001; Correction.

**SUMMARY:** On October 19, 2001 (66 FR 53242), the Department published a notice that announced the funding awards for Fiscal Year (FY) 2001 funding for its Indian Housing Drug Elimination Program. This document makes a correction to the list of funded applicants.

**FOR FURTHER INFORMATION CONTACT:** Please contact the office or individual identified in the notice published in the **Federal Register** on October 19, 2001 for further information.

**SUPPLEMENTARY INFORMATION:** On October 19, 2001 (66 FR 53242), the Department published a notice that announced the funding awards for Fiscal Year (FY) 2001 funding for its Indian Housing Drug Elimination Program. In Appendix A, Awarded Applicants, HUD incorrectly stated that the Housing Authority of the Cherokee Nation received a grant award. Through this document, HUD corrects the successful applicant's name.

Accordingly, FR Doc. 01-26333, Announcement of Funding Awards for the Indian Housing Drug Elimination Program for Fiscal Year 2001, published in the **Federal Register** on October 19, 2001 at 66 FR 53242, is corrected as follows:

- On page 53244, Appendix A.—Awarded Applicants FY 2001 Indian Housing Drug Elimination Program, is corrected to delete the Housing Authority of the Cherokee Nation from the list of awarded applicants, and to revise the Applicant name to read as follows: Cherokee Nation.

Dated: December 3, 2001.

**Michael Liu,**

*Assistant Secretary for Public and Indian Housing.*

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