

AMERICAN  
COLLEGE of  
CARDIOLOGY



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March 7, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

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**RE: Docket No. 01D-0519**

**Medical Devices: Draft Guidance on Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Availability**

The American College of Cardiology (ACC) is pleased to offer its comments on the Food and Drug Administration's (FDA) draft guidance document, "Cardiac Ablation Catheters Generic Arrhythmia Indications for Use," as announced in the December 7, 2001 *Federal Register* (66 Fed Reg 63,546).

The ACC is a 29,000-member non-profit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, leadership in the development of standards and guidelines, and the formulation of health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC supports the FDA's draft guidance allowing manufacturers of approved conventional cardiac ablation catheters to broaden their labeling from arrhythmia-specific indications to a generic arrhythmic treatment condition. The ACC agrees with the FDA's conclusion that the evidence from medical literature supports such a broadening of indications to a generic arrhythmia treating indication.

If you have any questions or concerns regarding the ACC's position, please contact ACC staff Alan Yount at 301-493-2352 or [ayount@acc.org](mailto:ayount@acc.org).

Sincerely,

Douglas P. Zipes, M.D., F.A.C.C.  
President

SPZ:lsm

01D-0519

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cc: Christine McEntee  
Anne B. Curtis, M.D., F.A.C.C.  
Eric N. Prystowsky, M.D. F.A.C.C.

*The mission of the American College of Cardiology is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, leadership in the development of standards and guidelines and the formulation of health care policy.*

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