

39.19. Contact the Manager, Regulations Group, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

Issued in Fort Worth, Texas, on April 15, 2003.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 02N-0434]

Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to withdraw certain advance notice of proposed rulemakings (ANPRMs), proposed rules, and other proposed actions that published in the **Federal Register** more than 5 years ago. These proposals rules are no longer considered viable candidates for final action at this time. FDA is taking this action to reduce its regulatory backlog and focus its resources on current public health issues. The FDA's actions are part of an overall regulatory reform strategy initiated by HHS Secretary Tommy G. Thompson.

DATES: Submit written or electronic comments by July 21, 2003.

ADDRESSES: Submit written comments 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: Lisa M. Helmanis, Regulations Policy and Management Staff (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3480.

SUPPLEMENTARY INFORMATION: On June 8, 2001, Secretary Thompson announced his regulatory reform initiative designed to reduce regulatory burdens in health care and respond faster to the concerns of health care providers, State, and local governments and individual Americans who are affected by HHS rules. In

December of 2001 the Secretary announced the membership of his Regulatory Reform Committee designed to carry out his initiative. In November of 2002 the Committee released its final report with over 255 specific recommendations for simplifying, streamlining and generally reducing the regulatory burden while continuing to require accountability by those doing business with HHS and its agencies. Over 25 of the recommendations have been adopted and the Secretary charged the Office of the Assistant Secretary for Planning and Evaluation to continue the efforts of the Regulatory Reform Committee. FDA's continuing efforts to withdraw regulations that have been proposed but not finalized are part of this overall initiative.

I. Background

In 1990, FDA began a comprehensive review of its regulations process that included a review of the backlog of advance notices of proposed rulemaking, notices of proposed rulemaking, and other notices for which no final action or withdrawal notice had been issued. In the **Federal Register** of August 28, 1991 (56 FR 42668), FDA announced its intent to withdraw 115 proposed rules published before December 31, 1985, that had never been finalized and invited comment on its intent. In the **Federal Register** of December 30, 1991 (56 FR 67440), FDA issued its first notice withdrawing 89 of those outstanding proposed rules. Again, in the **Federal Register** of January 19, 1993 (58 FR 4953), FDA announced its intent to withdraw 10 proposed rules that had never been finalized and invited comment on its intent. In the **Federal Register** of January 20, 1994 (59 FR 3042), the agency withdrew an additional 9 outstanding proposed rules.

Once again, FDA has reviewed its pending proposed rules and other notices that published in the **Federal Register** more than 5 years ago, and for which no final rule or notice of withdrawal has been issued. The agency has identified 84 such proposed rules and other actions that should be formally withdrawn. Included in this current list are 19 proposed rules that were included in the original 1991 list, but at that time, the agency decided to defer its decision to withdraw or finalize them until a later date. As with the other proposals it intends to withdraw, FDA believes that it is no longer appropriate to continue these rulemakings. These 19 proposed rules are identified in table 1 of this document.

As with the 1991 review, the agency undertook this most recent review because it believes that the backlog of pending proposals dilutes its ability to concentrate on higher priority regulations that are mandated by statute or necessary to address current public health issues. Because of the agency's limited resources and changing priorities, FDA has been unable to consider, in a timely manner, the issues raised by the comments on these proposals and either complete the action on them or withdraw the proposals. Additionally, because many of the proposals have become outdated in the time that has elapsed since their publication, the agency would need to obtain further comment on them before proceeding to final action. FDA has determined that the proposals identified in this document are lower in priority than those on the Unified Agenda and the Regulatory Plan. It is unlikely that the agency will have sufficient resources in the foreseeable future to further consider or prioritize these proposed rules. Although not required to do so by the Administrative Procedure Act or by regulations of the Office of the Federal Register, the agency believes the public interest is best served by withdrawing these 84 proposals. In some instances, the agency has already completed action on alternatives, e.g., the issuance of guidance or inclusion of provisions in related regulations, that have obviated the need to complete the proposed action.

If the agency does withdraw these proposals, that action would not preclude the agency from reinstituting proceedings to issue rules concerning the issues addressed in the proposals listed in table 1 of this document. Should FDA decide to undertake such a rulemaking sometime in the future, it will re-propose the actions and provide new opportunities for comment. For some proposals, the agency already has plans to institute new proceedings. Further, interested persons may submit a citizen petition requesting that the agency initiate rulemaking on any of the issues covered by the proposed rules that FDA intends to withdraw.

The agency advises that in some cases the preambles of these proposals may still reflect the current position of FDA on the matter addressed. In addition, withdrawal of a proposal is not intended to affect whatever utility the preamble statements may currently have as indications of FDA's position on a matter at the time the proposal was published.

Therefore, for the reasons set forth previously, and under the Federal Food, Drug, and Cosmetic Act, the agency