

[Federal Register: January 20, 1994]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
21 CFR Ch. I

[Docket No. 94N-0002]

Regulations Review Program Under Executive Order 12866

AGENCY: Food and Drug Administration, HHS.

ACTION: Plan for periodic review.

SUMMARY: The Food and Drug Administration (FDA) is announcing its plan to review significant regulations pursuant to Executive Order 12866, which requires all Federal agencies to develop a program for periodically reviewing existing significant regulations. Under this program, the agency will determine whether its regulations need to be refined to achieve their public health goals more effectively or to avoid unnecessary burdens.

DATES: Written comments by May 20, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Edwin V. Dutra, Jr., Regulations Policy and Management Staff (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION: Under section 5 of Executive Order 12866, each Federal agency must submit a plan to the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) for periodically reviewing its existing significant regulations. The goal is for agencies to determine whether existing significant regulations should be modified or eliminated to reduce their regulatory burden, to make the agency's regulatory program more effective, or to bring them into greater alignment with the President's priorities and the

principles set forth in the Executive Order. The Department of Health and Human Services has submitted a plan to OIRA, and this notice is being published as part of that plan.

Over the past 12 years, FDA has completed formal reviews of many of its important existing regulations. These reviews were similar to those required by Executive Order 12866. For example, the reviews identified requirements that were unjustified or unnecessary as a result of changed circumstances. The reviews eliminated those requirements, thereby reducing the regulatory burden. Each review also eliminated duplicative regulations where possible. Reviews have been completed for the following nine regulatory areas.

(1) Antibiotic Certification, 1982 (47 FR 39155, September 7, 1982): This final rule amended the antibiotic drug and new animal drug regulations to exempt all classes of antibiotic drugs from batch certification requirements, and amended the medical device regulations to exempt antibiotic susceptibility devices from batch certification. Under the exemptions, manufacturers are not required to obtain premarketing certification of each batch of antibiotic drug or antibiotic susceptibility device.

(2) New Drug Application Procedural Rules (the NDA Rewrite), 1985 (50 FR 7452, February 22, 1985): FDA revised its regulations governing the approval for marketing of new drugs and antibiotic drugs for human use. The revisions were intended to expedite the availability of beneficial drugs to consumers by improving the efficiency of FDA's approval process for new drugs and antibiotic drugs and to help applicants prepare and submit higher quality applications, thereby permitting FDA to review them more efficiently and with fewer delays.

(3) Rewrite of Blood Labeling Requirements, 1985 (50 FR 35458, August 30, 1985): FDA revised its regulations for blood labeling to simplify the requirements for transfusable blood and blood component products that are collected or manufactured in a blood bank establishment and to unify these requirements.

(4) Investigational New Drug Application Procedural Rules, 1987 (52 FR 8798, March 19, 1987): FDA revised its regulations governing the submission and review of investigational new drug applications (IND's). This action, along with the NDA Rewrite in 1985, was an effort to improve the agency's drug approval process. The revised regulations ensure FDA's ability to monitor investigations, while also facilitating the development of new beneficial drug therapies, and help sponsors of clinical investigations prepare and submit high-quality IND's and permit FDA to review them efficiently with minimal delay.

(5) Rewrite of Additional Standards for Reagent Red Blood Cells, 1987 (52 FR 37446, October 7, 1987): FDA revised the standards for reagent red blood cells to make them more flexible and to reflect current experience and scientific knowledge.

(6) Rewrite of Additional Standards for Blood Grouping Reagents,

1988 (53 FR 12760, April 19, 1988): FDA revised the standards for blood grouping reagents to make them more flexible and to reflect current experience and scientific knowledge.

(7) Methadone, 1989 (54 FR 8954, March 2, 1989): The conditions for use of methadone in the maintenance and detoxification treatment of narcotic addicts are provided in 21 CFR part 291 (the methadone regulation). The revisions to the methadone regulation were designed to streamline the regulation, to delete the requirement that treatment programs using methadone submit annual reports to FDA, and to promote more efficient operation of narcotic treatment programs. The rule also provided standards for long-term detoxification, as required by the Alcohol Abuse, Drug Abuse, and Mental Health Amendments of 1984 (Pub. L. 98-509), which revised the statutorily defined length of detoxification treatment from 21 days to 180 days.

(8) X-ray Standards, 1993 (58 FR 26386, May 3, 1993): A final rule was issued that simplified, clarified, and updated the original standard. These changes reflected the current technology.

(9) Food Labeling, 1993 (58 FR 2066 et seq., January 6, 1993): Beginning in 1989, and ultimately in response to the Nutrition Labeling and Education Act of 1990, FDA conducted a comprehensive review of the food label, including such issues as nutrition labeling, nutrient content claims for sodium, fat, cholesterol, and calories, and health claims. As part of this review, it considered the adequacy of its regulations implementing six misbranding sections of the act as well as its regulation on quantity of contents claims.

Due to limited resources, FDA prioritizes its reviews based on the following criteria: (1) Regulations that have a significant public health impact; (2) regulations that impose a significant burden on the agency and/or industry; and (3) regulations that impose no significant burden on the agency and/or industry. Cumulatively, the reviews listed above cover a significant majority of FDA's important regulations.

FDA's regulatory review program under Executive Order 12866 is as follows:

I. FDA-Initiated Review of Existing Regulations

FDA will continue the practice of reviewing its regulations on a continuing basis. These reviews are conducted on either an informal or a more formal basis. Informal reviews occur whenever FDA revises an existing regulation. The agency reviews the specific regulation being modified consistent with Executive Order 12866 to determine if it is still valid, and whether it should be updated based on current policy, data, and technology.

More formal reviews are undertaken consistent with available resources and regulatory priorities when FDA believes that changed circumstances create an opportunity to improve the effectiveness and

efficiency of existing regulations or to reduce regulatory burden. Examples are listed above. FDA is currently conducting such reviews of regulations in the following areas:

(1) Medical Devices; Recordkeeping and Reporting for Electronic Products

(2) Medical Devices; Current Good Manufacturing Practice

(3) Hearing Aids

(4) Investigational New Animal Drug Applications Procedural Rules

(5) New Animal Drug Application (NADA) Procedural Rules

(6) NADA Records and Reports.

In addition, FDA's Center for Biologics Evaluation and Research (CBER) is in the process of establishing two task forces to perform reviews of all blood regulations and administrative and licensing regulations. CBER will conduct these reviews based on standards that incorporate the elements of Executive Order 12866.

FDA invites public comment on other regulations that warrant review and possible revision to more effectively achieve the agency's public health and regulatory objectives, reduce burdens on regulated industries and other affected parties, or better conform to the priorities and principles set forth in Executive Order 12866. Suggestions should be accompanied by specific examples of regulations that need to be reviewed, the improvement to be achieved, and the criteria contained in the Executive Order 12866 under which such a review should be focused.

Executive order 12866 requires agencies to identify any legislative mandates that require the agency to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances. FDA invites public comment on this issue.

II. FDA Reduction of Backlog of Pending Proposed Regulations

As part of FDA's regulations streamlining initiative begun in 1991, the agency instituted an annual review of outstanding advance notices of proposed rulemaking, notices of proposed rulemaking, and other notices concerning proposed actions that had not been made final. In the Federal Register of December 30, 1991, the agency withdrew 89 outstanding proposals, and elsewhere in this issue FDA is withdrawing an additional 9 proposals. When the annual review identifies proposed rules as outdated, no longer necessary, or, based on agency priorities, unlikely to be completed in the foreseeable future, FDA will publish a notice of intent to withdraw those proposals in the Federal Register. FDA will continue this periodic review to help the agency, regulated industries, and other affected parties focus more effectively on FDA's active rulemaking agenda. The agency invites public comment on other proposed actions that could be considered for withdrawal.

III. Citizen Petitions Process

Under FDA's procedural regulations any interested party may petition the agency. The petition process is a mechanism often used by industry and the public to request that the agency amend, revoke, or create a regulation. FDA encourages the continued use of citizen petitions as a means of identifying those FDA regulations which should be candidates for review under Executive Order 12866.

Interested persons may, on or before May 20, 1994, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 11, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

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