dated October 2, 1997, including Appendix 01 (for Model A300–600 series airplanes); as applicable; at the applicable time specified in paragraph (a)(1) or (a)(2) of this AD. Thereafter, repeat the inspection at intervals not to exceed 5 years.

(1) For airplanes with less than 15 years since date of manufacture as of the effective date of this AD: Inspect within 10 years since date of manufacture, or within 12 months after the effective date of this AD, whichever occurs later.

(2) For airplanes with 15 or more years since date of manufacture as of the effective date of this AD: Inspect within 6 months after the effective date of this AD.

Note 2: For Model A300 series airplanes, accomplishment of an eddy current inspection prior to the effective date of this AD in accordance with Airbus Service Bulletin A300–53–0339, dated October 2, 1997, is considered acceptable for compliance with the initial eddy current inspection required by paragraph (a) of this AD.

Corrective Actions

(b) If any crack is detected during any inspection required by paragraph (a) of this AD, prior to further flight, repair the door edge frame in accordance with Airbus Service Bulletins A300–53–0339, Revision 1, dated July 28, 1998 (for Model A300 series airplanes); A310–53–2106 (for Model A310 series airplanes), dated October 2, 1997; or A300–53–6114 (for Model A300–600 series airplanes), dated October 2, 1997; as applicable. Complete replacement of a door edge frame with a new door frame in accordance with the service bulletin constitutes terminating action for the repetitive inspections required by this AD for that door frame only.

Report Requirements

(c) Submit a report of the inspection results (both positive and negative findings) to Airbus Industrie, Customer Services Directorate, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, at the applicable time specified in paragraph (e)(1) or (e)(2) of this AD. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(1) For airplanes on which any inspection is accomplished after the effective date of this AD: Submit the report within 30 days after performing any inspection required by paragraph (a) or (b) of this AD.

(2) For airplanes on which the inspection has been accomplished prior to the effective date of this AD: Submit the report within 10 days after the effective date of this AD.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in French airworthiness directive 98–123–245(B), dated March 11, 1998.

Issued in Renton, Washington, on December 28, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–48 Filed 1–3–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. 99N–4490]

Additions to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to add two drug products to the list of drug products that may not be used for pharmacy compounding under the exemptions provided by the Federal Food, Drug, and Cosmetic Act (the act) because they have had their approval withdrawn or were removed from the market because the drug product or its components have been found to be unsafe or not effective.

DATES: Written comments must be received on or before March 20, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

President Clinton signed the Food and Drug Administration Modernization Act (Public Law 105–115) into law on November 21, 1997. One of the issues addressed in the legislation is the applicability of the act to the practice of pharmacy compounding. Compounding involves a process whereby a pharmacist or physician combines, mixes, or alters ingredients to create a customized medication for an individual patient. Section 127 of the Modernization Act, which adds section 503A to the act (21 U.S.C. 353a), describes the circumstances under which compounded drugs qualify for exemptions from certain adulteration, misbranding, and new drug provisions of the act (i.e., sections 501(a)(2)(B), 502(f)(1), and 505 of the act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355)).

Section 503A of the act contains several conditions that must be satisfied for pharmacy compounding to qualify for the exemptions. One of the conditions is that the licensed pharmacist or licensed physician does not ''compound a drug product that appears on a list published by the Secretary in the **Federal Register** of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.''

II. Rulemaking to Establish the List

In the **Federal Register** of October 8, 1998 (63 FR 54082), we proposed the original list of drug products that have had their approval withdrawn or were removed from the market because the drug product or its components have been found to be unsafe or not effective. We published the original list as a final rule in the **Federal Register** of March 8, 1999 (64 FR 10944). You may wish to read these documents for additional information about the list. The two **Federal Register** documents may be found on the Center for Drug Evaluation and Research's website at http://www.fda.gov/cder/pharmcomp/default.htm or the Government Printing Office's website at http://www.access.gpo.gov/su docs/aces/aces140.html.

The list was codified as § 216.24 of Title 21 in the Code of Federal Regulations (CFR) (21 CFR 216.24). This is the first time we have proposed to amend the list.

III. Description of this Proposed Rule

We are proposing that the drug products described below be added to

the list of drug products that have had their approval withdrawn or were removed from the market because the drug product or its components have been found to be unsafe or not effective. Compounding a drug product that appears on the list is not covered by the exemption provided in section 503A(a) of the act, and it may be subject to enforcement action under sections 501(a)(2)(B), 502(f)(1), and 505 (among other applicable provisions) of the act.

Aminopyrine: All drug products containing aminopyrine. Drug products containing aminopyrine were used as an analgesic and an antipyretic. Aminopyrine caused agranulocytosis, a condition characterized by a decrease in the number of certain white blood cells and lesions on the mucous membrane and skin. Some of the cases of agranulocytosis were fatal. In 1964, we declared drug products containing aminopyrine to be new drugs. We invited new drug applications (NDA's) for these drug products, but only for use as an antipyretic in serious situations where other safer drugs could not be used (see 21 CFR 201.311 (42 FR 53954, October 4, 1977)). We received no NDA's for drug products containing aminopyrine, and those unapproved drug products were removed from the market by their manufacturers (see 42 FR 53954).

Astemizole: All drug products containing astemizole. Astemizole tablets were marketed under the trade name Hismanal and were indicated for the relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria. We approved the NDA for astemizole tablets in December 1988. Within a few years of the approval, it was learned that low-level overdosages of astemizole were resulting in life-threatening heart arrhythmias. Patients with liver dysfunction or who were taking other drugs that interfered with the metabolization of astemizole were also found to be at risk of serious cardiac adverse events while taking astemizole. The manufacturer of astemizole tablets, the only astemizole drug product, removed the product from the market on June 18, 1999. We published a notice in the **Federal Register** of August 23, 1999 (64 FR 45973), announcing our determination that astemizole tablets were withdrawn from the market for safety reasons.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. As discussed below, the agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The agency has not estimated any compliance costs or loss of sales due to this proposed rule because it prohibits pharmacy compounding of only those drug products that have already been withdrawn or removed from the market. Although the agency is not aware of any routine use of these drug products in pharmacy compounding, the agency invites the submission of comments on this issue and solicits current compounding usage data for these drug products.

Unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant economic impact of a regulation on small entities. The agency is taking this action to comply with section 503A of the act. This provision specifically directs us to develop a list of drug products that have been withdrawn or removed from the market because such products or components have been found to be unsafe or not effective. Any drug product on this list will not qualify for the pharmacy compounding exemptions under section 503A of the act.

The drug products that are proposed to be added to the this list were manufactured by several different pharmaceutical firms, some of which may have qualified under the Small Business Administration (SBA) regulations (those with less than 750 employees) as small businesses. However, since the list only includes drug products that have already been withdrawn or removed from the market for safety or efficacy concerns, this proposal will not negatively impact these small businesses. Moreover, no compliance costs are estimated for any of these small pharmaceutical firms because they are not the subject of this rule and are not expected to realize any further loss of sales due to this proposal. Further, the SBA guidelines limit the definition of small drug stores or pharmacies to those that have less than $5.0 million in sales. Again, the pharmacies that qualify as small businesses are not expected to incur any compliance costs or loss of sales due to this regulation because the products have already been withdrawn or removed from the market, and the agency believes that these drugs would be compounded only very rarely, if ever. Therefore, we certify that this rule will not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million (adjusted annually for inflation) in any one year. The publication of the list of products withdrawn or removed from the market because they were found to be unsafe or ineffective will not result in expenditures of funds by State, local, and tribal governments or the private sector in excess of $100 million annually. Because the agency does not estimate any annual expenditures due to the proposed rule, we are not required to perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

VI. Paperwork Reduction Act of 1995

We tentatively conclude that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Request for Comments

Interested persons may, on or before March 20, 2000, submit to the Dockets

Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects in 21 CFR Part 216

Drugs, Pharmacy compounding, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 216 be amended as follows:

PART 216—PHARMACY COMPOUNDING

1. The authority citation for 21 CFR part 216 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353a, 355, and 371.

2. Amend § 216.24 by adding alphabetically to the list of drug products ''Aminopyrine'' and ''Astemizole'' to read as follows:

§ 216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

* * * * *

Aminopyrine: All drug products containing aminopyrine.

Astemizole: All drug products containing astemizole.

* * * * *

Dated: December 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–76 Filed 1–3–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–105606–99]

RIN 1545–AX05

Credit for Increasing Research Activities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the computation of the credit for increasing research activities (the research credit) for members of a controlled group and the allocation of the credit under section 41(f) of the Internal Revenue Code. These proposed regulations are intended to provide guidance on the proper method for computing the research credit for members of a controlled group and the proper method for allocating the group credit to members of the group. These proposed regulations reflect changes to section 41 made by the Revenue Reconciliation Act of 1989 (the 1989 Act). This document also provides notice of a public hearing on these regulations.

DATES: Written or electronic comments must be received no later than April 5, 2000. Outlines of topics to be discussed at the public hearing scheduled for April 26, 2000 at 10 a.m. must be received by April 5, 2000.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG–105606–99), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–105606–99), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option of the IRS Home Page, or by submitting comments directly to the IRS Internet site at: http://www.irs.gov/prod/taxregs/regslist.html. The public hearing will be held in room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Lisa J. Shuman at (202) 622–3120 (not a toll-free number); concerning submission of comments, the hearing, and/or to be placed on the building access list to attend the hearing, La Nita Van Dyke at (202) 622–7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, OP:FS:FP, Washington, DC 20224. Comments on the collection of information should be received by March 6, 2000. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is contained in the preamble under the heading ''Proposed Effective Date.'' The information is required by the IRS to ensure that members of a controlled group filing claims for refund based on a change in method of allocating the research credit to members of the group do not together claim in excess of 100% of the credit with respect to prior taxable years.

Estimated total annual reporting burden: 200 hours.

Estimated average annual burden hours per respondent: 20 hours.

Estimated number of respondents: 10.

Estimated frequency of responses: On occasion.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

The research credit provisions originally appeared in section 44F of the Internal Revenue Code of 1954 (the 1954 Code), as added to the 1954 Code by section 221 of the Economic Recovery Tax Act of 1981. Section 471(c) of the Tax Reform Act of 1984 redesignated section 44F as section 30. Section 231