

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

2002-09-13 Cessna Aircraft Company:
Amendment 39-12746; Docket No. 2002-CE-17-AD.

(a) *What airplanes are affected by this AD?*
This AD applies to the following airplane models and serial numbers that are certificated in any category:

Model	Serial Nos.
CESSNA 441	0001 through 0362; and 698.

(b) *Who must comply with this AD?*
Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?*
The actions specified by this AD are intended to detect and correct chafing and/or arcing boost pump wiring, which could result in arcing within the wing fuel system. Such failure could lead to ignition of explosive vapor within the fuel storage system.

(d) *What must I do to address this problem?* To address this problem, you must accomplish the following actions:

Actions	Compliance	Procedures
(1) Inspect the 5718106-1 wire harness and fuel boost pump lead wires for chafing or damage.	Within the next 25 hours time-in-service (TIS) after May 31, 2002 (the effective date of this AD) or 60 days after May 31, 2002 (the effective date of this AD), whichever occurs first.	In accordance with Cessna Conquest Service Bulletin No.: CQB02-1R1, Revision 1, dated April 22, 2002.
(2) If any wire harness or fuel boost pump lead wires are found chafed or damaged during the inspection required in paragraph (d)(1) of this AD, repair or replace the harness or lead wires.	Before further flight, after the inspection required in paragraph (d)(1) of this AD.	In accordance with Cessna Conquest Service Bulletin No.: CQB02-1R1, Revision 1, dated April 22, 2002.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Wichita ACO, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Robert Adamson, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: 316-946-4145; facsimile: 316-946-4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Cessna Conquest Service Bulletin No.

CQB02-1R1, Revision 1, dated April 22, 2002. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; telephone: (316) 517-5800; facsimile: (316) 942-9006. You may view this information at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on May 31, 2002.

Issued in Kansas City, Missouri, on May 1, 2002.

Michael Gallagher,
Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02-11523 Filed 5-8-02; 8:45 am]

BILLING CODE 4910-13-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1240

[Notice (02-054)]

RIN 2700-AC47

Inventions and Contributions

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: NASA is amending its regulation to provide definitions, to add a new category of initial awards for

release of software, to provide initial awards for the issuance of patents based upon continuation-in-part and divisional patent applications, to increase the amount of certain awards, and to change delegations of authority from the NASA Administrator.

EFFECTIVE DATE: May 9, 2002.

ADDRESSES: Inventions and Contributions Board, Code RI, National Aeronautics and Space Administration, Washington, DC 20546-0001.

FOR FURTHER INFORMATION CONTACT: Mr. Walter D. Hussey Director of Staff, Inventions and Contributions Board, 202-358-2468.

SUPPLEMENTARY INFORMATION: To aid the NASA Inventions and Contributions Board in processing applications for awards, all applications must now be submitted using electronic media.

NASA now provides initial awards for the filing of a non-provisional U.S. patent application, or upon the issuance of a patent for a continuation-in-part or a divisional patent application, for an invention made and reported by an employee of NASA or an employee of a NASA contractor. The amounts of these awards are at least \$1,000 for a sole inventor and at least \$500 for each joint inventor. Also, no additional award is authorized for a continuation of a patent application where an initial award was authorized for the parent application and the parent application will be or has been abandoned. Furthermore, initial awards are not authorized for provisional applications under 35 U.S.C

111(b) or reissue applications under 35 U.S.C. 251.

Initial awards are authorized for the approved release to a qualified user of a software package based on an innovation made and reported by an employee of NASA or a NASA contractor. The amounts of these initial awards are at least \$1,000 for a sole innovator and at least \$500 for joint innovators. The Board is authorized to recommend a supplemental monetary award in an amount that will be based on an evaluation of the technical and commercial merits of the innovation. No contribution may receive an award unless NASA has an ownership interest in the software, the software is of commercial quality, the software has been verified, and the software has been distributed to qualified users. Lastly, awards for software release are not eligible to receive a Selected Tech Brief award based upon the publication of an announcement of availability in "NASA Tech Briefs."

Initial awards for the publication of a selected innovation in "NASA Tech Briefs" has been increased to at least \$350 from the previous amount of at least \$150.

The Board will now recommend an award for a contribution to NASA, where upon evaluation of its scientific and technical merits, it is determined to warrant an award of at least \$500. Previously, the threshold was set at \$250.

The maximum amount that may be paid for any innovation within any single category of initial award may not exceed \$5,000.

The Associate Administrator for Aerospace Technology, and the Chairperson, Inventions and Contributions Board, are both delegated authority to execute grants of awards for scientific and technical contributions to NASA not to exceed \$2,000 per contributor. Also, the Chairperson, Inventions and Contributions Board, is delegated the authority to make initial awards.

Lastly, a definitions section has been added to this subpart.

List of Subjects in 14 CFR Part 1240

Decorations, Medals, Awards, Government contracts, Government employees, Inventions and patents.

For reasons set out in the Preamble, 14 CFR part 1240 is revised to read as follows:

PART 1240—INVENTIONS AND CONTRIBUTIONS

Subpart 1—Awards for Scientific and Technical Contributions

Sec.

- 1240.100 Purpose.
- 1240.101 Scope.
- 1240.102 Definitions.
- 1240.103 Criteria.
- 1240.104 Applications for awards.
- 1240.105 Special procedures—NASA and NASA contractor employees.
- 1240.106 Review and evaluation of contribution.
- 1240.107 Notification by the Board.
- 1240.108 Reconsideration.
- 1240.109 Hearing procedure.
- 1240.110 Recommendation to the Administrator.
- 1240.111 Release.
- 1240.112 Presentation of awards.
- 1240.113 Financial accounting.
- 1240.114 Delegation of authority.

Authority: Section 306 of the National Aeronautics and Space Act of 1958, as amended (42 U.S.C. 2458), and the Federal Technology Transfer Act of 1986, sec. 12, 15 U.S.C. 3710b(1).

Subpart 1—Awards for Scientific and Technical Contributions

§ 1240.100 Purpose.

This subpart prescribes procedures for submitting applications for monetary awards to the Administrator of NASA for scientific and technical contributions which have significant value in the conduct of aeronautical and space activities pursuant to 42 U.S.C. 2458, and establishes the awards program consistent with the Federal Technology Transfer Act of 1986, section 12, 15 U.S.C. 3710b(1).

§ 1240.101 Scope.

This subpart applies to any scientific or technical contribution, whether or not patentable, which is determined by the Administrator after referral to the Inventions and Contributions Board to have significant value in the conduct of aeronautical and space activities for which an application for award has been submitted to NASA under 42 U.S.C. 2458.

§ 1240.102 Definitions.

As used in this subpart:

- (a) *Administrator* means the Administrator of the National Aeronautics and Space Administration.
- (b) *Board* means the NASA Inventions and Contributions Board.
- (c) *Chairperson* means the Chairperson of the NASA Inventions and Contributions Board.
- (d) *Commercial quality* refers to computer software that is not in an experimental or beta phase of development, that performs in

accordance with its specifications, and includes documentation describing the software's form and function.

(e) *Contract* means any contract, agreement, understanding, or other arrangement with NASA or another Government Agency on NASA's behalf, including any assignment, substitution of parties, or subcontract executed or entered into thereunder.

(f) *Contractor* means the party who has undertaken to perform work under a contract or subcontract.

(g) *Innovation* means a mathematical, engineering or scientific concept, idea, design, process, or product, reported as new technology on NASA Form 1679.

(h) *Innovator* means any person listed as a contributor, inventor, or author of an innovation.

(i) *Invention* includes any act, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States or any foreign country.

(j) *Qualified User* means any person that has legally acquired computer software and has the right to use it for a legal purpose.

(k) *Verified* means passing rigorous testing to ascertain whether the functionality claimed in the innovation's documentation is realized.

§ 1240.103 Criteria.

(a) Only those contributions to NASA which have been:

(1) Used in a NASA program or adopted or sponsored or supported by NASA, and

(2) Found to have significant value in the conduct of aeronautical and space activities, will be recommended for award under this subpart.

(b) In determining the amount, terms, and conditions of any award, the following criteria will be considered:

(1) The value of the contribution to the United States;

(2) The aggregate amount of any sums which have been expended by the applicant for the development of such contribution;

(3) The amount of any compensation (other than salary received for services rendered as an officer or employee of the Government) previously received by the applicant for or on account of the use of such contributions by the United States; and

(4) Such other factors as the Administrator shall determine to be material.

§ 1240.104 Applications for awards.

(a) *Eligibility.* Applications for award may be submitted by any person

including any individual, partnership, corporation, association, institution, or other entity.

(b) *Information required.* Applications for award should be addressed to the Inventions and Contributions Board (herein referred to as the Board), National Aeronautics and Space Administration, Washington, DC 20546-0001, and will contain:

(1) The name and address of the applicant, the person's relationship to the contributor if the contribution is made by one other than the applicant, and the names and addresses of any others having information as to the value or usage of the contribution;

(2) A complete written description of the contribution, in the English language, using electronic media, accompanied by drawings, sketches, diagrams, or photographs illustrating the nature of the contribution and the technical and scientific principles upon which it is based, any available test or performance data or observations of pertinent scientific phenomena, and the aeronautics or space application of the contribution;

(3) The date and manner of any previous submittal of the contribution to any other United States Government agency, and the name of such agency;

(4) The aggregate amount of any sums which have been expended by the applicant for the development of the contribution;

(5) The nature and extent of any known use of the contribution by the United States and by any agency of the United States Government;

(6) The amount of any compensation (other than salary received for services rendered as an officer or employee of the Government) previously received by the applicant for or on account of the use of such contribution by the United States;

(7) Identification of any United States and foreign patents applied for or issued relating to the contribution; and

(8) An agreement to surrender all claims which such applicant may have for the use of such contribution by the Government.

(c) *General.* (1) Each contribution will be made the subject of a separate application in order that each contribution may be evaluated individually.

(2) Material constituting a possible hazard to safety or requiring unusual storage facilities should not be submitted, and will not be accepted. Models or intricate exhibits demonstrating the contribution will not be accepted unless specifically requested by the Board. In those few cases where such models or exhibits

have been submitted pursuant to a request made by the Board, the same will be returned to the applicant upon written request from the applicant.

(3) It is the policy of the Board to use or disclose information contained in applications for awards for evaluation purposes only. Applications for awards submitted with restrictive legends or statements differing from this policy will be treated in accordance with the Board's policy.

§ 1240.105 Special procedures—NASA and NASA contractor employees.

(a) A NASA Headquarters office, a NASA field installation, or a NASA contractor may submit to the Board an application for an award identifying the originator(s) of any scientific or technical contribution conceived or developed during the performance of a NASA program or contract, and which is considered to be of value in advancing the state of knowledge in space or aeronautical activities, whether or not the contribution is the subject of a NASA Tech Brief, software approved for public release, or of a U.S. patent application.

(b) The Board will recommend to the Administrator or a designee that an initial award of at least \$1,000 be granted to a sole inventor, or \$500 each to joint inventors, upon submittal of NASA Form 1688 by either the Associate General Counsel for Intellectual Property, for an invention made and reported by a NASA Headquarters employee or an employee of a NASA Headquarters contractor, or a patent counsel at a NASA field installation for an invention made and reported by an employee of that installation or by an employee of an installation contractor, has filed a nonprovisional U.S. patent application or that a continuation-in-part or divisional patent has been issued. The Board is authorized to recommend a supplemental monetary award in an amount that will be based on the evaluation of the technical and commercial merits of the invention. No additional award will be given for a continuation patent application where an initial award was authorized for the parent application and this parent application will be or has been abandoned. In addition, initial awards will not be granted for provisional applications under 35 U.S.C. 111(b) or reissue applications under 35 U.S.C. 251.

(c) When the Board receives written notice (NASA Form 1688) that a NASA Center has approved for release to qualified users a software package based on an innovation made and reported by

an employee of NASA or a NASA contractor on NASA Form 1679, the Board will recommend to the Administrator or designee that an initial award of at least \$1,000 be granted to a sole innovator, and an award of at least \$500 will be granted to each originator of the innovation if there is more than one. The Board is authorized to recommend a supplemental monetary award in an amount that will be based on the evaluation of the technical and commercial merits of the innovation. No contribution may receive this award unless:

(1) NASA has an ownership interest in the software; i.e., NASA has the unrestricted use of the software in perpetuity at no charge from any other entity;

(2) The software is of commercial quality; i.e., is not in experimental or beta phases of development and includes documentation, either in paper or electronic formats, describing the software's form and function;

(3) The software has been verified to perform the functions claimed in its documentation on the platform for which it was designed without harm to the systems or data contained within; and,

(4) The software has been distributed to qualified users upon the written approval for release by Center management.

(d) Software dissemination awards are not eligible to receive selected Tech Brief awards based upon the publication of an announcement of availability in "NASA Tech Briefs."

(e) When the Board receives written notice (NASA Form 1688) that a NASA Center has approved for publication a selected NASA Tech Brief based on an innovation made and reported by an employee of NASA or a NASA contractor on NASA Form 1679, the Board will recommend to the Administrator or designee that an initial award of at least \$350 be granted, and an award of at least that amount will be granted to each originator of the innovation. The Board is authorized to recommend a supplemental monetary award in an amount that will be based on the evaluation of the technical and commercial merits of the innovation.

(f) When a selected NASA Tech Brief has been approved for publication, and/or a NASA Center has approved the release of a software package, and/or the filing of a U.S. patent application has been authorized for the same contribution, the initial awards authorized in paragraphs (b), (c), and (e) of this section will be cumulative.

(g) Initial awards authorized in paragraphs (b), (c), and (e) of this

section may not exceed a total of \$5,000 per category. Such cases, wherein a large number of multiple innovators are contributors, must be submitted for formal evaluation by the Board on a NASA Form 1329 or 1329A.

(h) Awards authorized in paragraphs (a), (b), (c), and (e) of this section will not be granted to a contributor who has previously received full compensation for, or on account of, the use of such a contribution by the United States.

(i) If a contribution, as first reported and evaluated, is judged not to merit a supplemental award, as provided for in paragraphs (a), (b), (c), or (e) of this section, or the contribution is later proved to be of more significant value, it may be submitted for reevaluation on NASA Form 1329A. Responsible NASA and NASA contractor officials are encouraged to periodically review such reported contributions, and to resubmit them for reconsideration through the same channels as originally reported.

§ 1240.106 Review and evaluation of contribution.

(a) A contribution will be initially reviewed by the Board on the basis of the material submitted by the applicant under § 1240.104(b).

(b) If it is determined that the contribution has been used in a NASA program, or adopted or sponsored or supported by NASA, the contribution will be evaluated for its significant value in the conduct of aeronautical or space activity.

(c) The Board will recommend an award for such contribution when, upon evaluation of its scientific and technical merits, it is determined to warrant an award of at least \$500.

§ 1240.107 Notification by the Board.

(a) With respect to each completed application where the Board has recommended to the Administrator the granting of an award, and the Administrator has approved such award, the Board will notify the applicant of the amount and terms of the award. In the case of NASA employees or employees of NASA contractors, such notification will normally be made through the appropriate NASA field installation representative.

(b) Except for applications from NASA employees or employees of NASA contractors, where the Board does not propose to recommend to the Administrator the granting of an award, a notification will be provided which includes a brief statement of the reasons for such decision.

§ 1240.108 Reconsideration.

(a) In those cases where the Board does not recommend an award, the applicant may, within such period as the Board may set but in no event less than 30 days from notification, request reconsideration of the Board's decision.

(b) If reconsideration has been requested within the prescribed time, the applicant will, within 30 days from the date of the request for reconsideration, or within any other time as the Board may set, file its statement setting forth the issues, points, authorities, arguments, and any additional material on which it relies.

(c) Upon filing of the reconsideration statement by the applicant, the case will be assigned for reconsideration by the Board upon the contents of the application, the record, and the reconsideration statement submitted by the applicant.

(d) If after reconsideration, the Board again does not propose to recommend the granting of an award, the applicant, after such notification by the Board, may request an oral hearing within the time set by the Board.

(e) An oral hearing without reconsideration may be granted upon determination of the Chairperson that good cause exists to do so.

§ 1240.109 Hearing procedure.

(a) An Oral hearing held by the Board will be in accordance with the following procedures:

(1) If the applicant requests a hearing within the time set in accordance with § 1240.108(d) or (e), the Board will set a place and date for such hearing and notify the applicant.

(2) The applicant may be represented by an attorney or any other appropriately designated person.

(3) Hearings will be open to the public unless the applicant requests that a closed hearing be held.

(4) Hearings may be held before the full membership of the Board or before any panel of Board members designated by the Chairperson.

(5) Hearings will be conducted in an informal manner with the objective of providing the applicant with a full opportunity to present evidence and arguments in support of the application. Evidence may be presented through means of such witnesses, exhibits, and visual aids as are arranged for by the applicant. While proceedings will be ex parte, members of the Board and its counsel may address questions to witnesses called by the applicant, and the Board may, at its option, utilize the assistance and testimony of technical advisors or other experts.

(6) Subject to the provisions of § 1240.104(c)(2), the applicant will submit a copy of any exhibit or visual aid utilized unless otherwise directed by the Board. The Board may, at its discretion, arrange for a written transcript of the proceedings and a copy of such transcript will be made available by the recorder for purchase by the applicant.

(7) No funds are available to defray traveling expenses or any other cost incurred by the applicant.

§ 1240.110 Recommendation to the Administrator.

Upon a determination by the Board that a contribution merits an award, the Board will recommend to the Administrator or a designee the terms and conditions of the proposed award, including a specific amount and distribution thereof for any multiple contributors. The recommendation of the Board to the Administrator or designee will reflect the views of the majority of the Board members. Dissenting views may be transmitted with the majority opinion.

§ 1240.111 Release.

Under subsection 306(b)(1) of the National Aeronautics and Space Act of 1958, as amended, no award will be made to an applicant unless the applicant submits a duly executed release, in a form specified by the Administrator, of all claims the applicant may have to receive any compensation (other than the award recommended) from the United States Government for use of the contribution or any element thereof at any time by or on behalf of the United States, or by or on behalf of any foreign government pursuant to any existing or future treaty or agreement with the United States, within the United States, or at any other place.

§ 1240.112 Presentation of awards.

(a) Monetary awards and accompanying written acknowledgments to employees of NASA will be presented in a formal ceremony by the appropriate Official-in-Charge at the Headquarters Office, or by the Director of the cognizant field installation or designee.

(b) Monetary awards and accompanying written acknowledgments to employees of NASA contractors will be forwarded to contractor officials for suitable presentation.

§ 1240.113 Financial accounting.

(a) An Award Check Receipt (NHQ DIV Form 622), which accompanies the transmittal of each group of award

checks from the Board will be dated and signed by the responsible NASA Center representative and returned to the Board without delay.

(b) Not later than December 10 of each year, the responsible field installation official will submit a report certifying that all award checks, which were issued and received by the field installation during the year, have been delivered to the proper employees of NASA and employees of NASA contractors. In the case of those checks that have not been delivered by December 10, the certification report will be accompanied by all undelivered checks and a brief explanation of the reasons for the failure to make delivery. This annual certification report is essential in order to ensure that income and withholding tax totals for all awardees are correct and complete at the close of each calendar year.

§ 1240.114 Delegation of authority.

(a) The Associate Administrator for Aerospace Technology and the Chairperson, Inventions and Contributions Board, are delegated authority to execute grants of awards for significant scientific or technical contributions not exceeding \$2,000 per contributor, when in accordance with the recommendation of the Board and in conformity with applicable law and regulations.

(b) The Chairperson, Inventions and Contributions Board, is delegated authority to execute grants of initial awards upon the decision to file for a U.S. patent application, release software to qualified users, and/or upon approval to publish a selected NASA Tech Brief.

(c) No redelegation is authorized except by virtue of succession.

(d) The Chairperson, Inventions and Contributions Board, will ensure that feedback is provided so that the Administrator, through official channels, is immediately informed of significant actions, problems, or other matters of substance related to the exercise of the authority delegated in this section.

Dated: May 2, 2002.

Sean O'Keefe,
Administrator.

[FR Doc. 02-11513 Filed 5-8-02; 8:45 am]

BILLING CODE 7510-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 80N-0280]

RIN 0910-AA01

Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule stating that a certain ingredient in over-the-counter (OTC) drug products is not generally recognized as safe and effective or is misbranded. FDA is issuing this final rule after considering the reports and recommendations of various OTC drug advisory review panels and public comments on proposed agency regulations. This final rule addresses the ingredient octoxynol 9, considered in the rulemaking for OTC vaginal contraceptive drug products. Based on the failure of interested parties to submit new data or information to FDA under the proposed regulation, the agency has determined that the presence of this active ingredient in an OTC drug product would result in that drug product not being generally recognized as safe and effective for its intended use or would result in misbranding. This final rule is part of FDA's ongoing OTC drug product review.

DATES: This regulation is effective November 5, 2002.

FOR FURTHER INFORMATION CONTACT: Helen Cothran, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of November 7, 1990 (55 FR 46914), FDA published under § 330.10(a)(7)(ii) (21 CFR 330.10(a)(7)(ii)) a final rule on the status of certain OTC drug Category II and III active ingredients. That final rule declared as not generally recognized as safe and effective certain active ingredients that had been proposed as nonmonograph (Category II or III) under the agency's OTC drug review. The periods for submission of comments and new data following the publication of a notice of proposed rulemaking had closed and no significant comments or

new data had been submitted to upgrade the status of these ingredients. In each instance, a final rule for the class of ingredients involved had not been published to date.

In the *Federal Register* of May 10, 1993 (58 FR 27636), FDA published a final rule establishing that certain additional active ingredients in OTC drug products are not generally recognized as safe and effective or are misbranded. That final rule included active ingredients from a number of OTC drug rulemakings that were not covered by the November 7, 1990, final rule (see table I of the May 10, 1993, final rule (58 FR 27636 at 27639 to 27641) for a list of OTC drug rulemakings and active ingredients covered by that final rule).

In the proposed rulemaking for OTC vaginal contraceptive drug products (45 FR 82014, December 12, 1980), the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products (the Panel) placed nonoxynol 9 and octoxynol 9 in Category I (safe and effective), placed phenylmercuric acetate, phenylmercuric nitrate, and other compounds containing mercury in Category II for safety, and placed dodecaethylene glycol monolaurate (polyethylene glycol 600 monolaurate), laureth 10S, and methoxypolyoxyethylene glycol 550 laurate in Category III for efficacy. In the preamble to the Panel's report (45 FR 82014), the agency stated that clinical trials of each product or final formulation may be the only certain predictor of its effectiveness in humans. The agency further stated that if clinical trials are necessary, manufacturers may be required to submit a new drug application (NDA) or supplement an existing NDA. The agency stated that it would announce its decision in a separate *Federal Register* document or in the tentative final order.

In the proposed rule for OTC vaginal contraceptive drug products (60 FR 6892, February 3, 1995), the agency proposed that manufacturers of OTC vaginal contraceptive drug products obtain approved applications for marketing of their products. The agency took this action because the evidence currently available shows that effectiveness of these products is dependent upon the final formulation and clinical studies in humans are needed to establish the effectiveness of the active ingredients in OTC vaginal contraceptive drug products. Therefore, each product must be tested in appropriate clinical trials under actual conditions of use. FDA encouraged manufacturers to consult with the agency regarding testing and the