pharmaceutical necessities or preservatives and not as active ingredients.

References

1. OTC Vol. 110004.
2. OTC Vol. 110005.
3. OTC Vol. 110006.
4. OTC Vol. 110017.
5. OTC Vol. 110018.
6. OTC Vol. 110021.

E. Comments on Testing Guidelines

25. Numerous comments criticized the safety and effectiveness testing guidelines recommended by the Panel to upgrade a vaginal contraceptive ingredient from Category III to Category I (45 FR 82014 at 82020 and 82043). Generally, the comments stated that the guidelines are unclear, needlessly specific, unnecessary, or based on unsound logic. Some of the comments subsequently proposed using alternative testing methods, while others urged elimination of certain methods.

The agency has not addressed specific testing guidelines in this document. In revising the OTC drug review procedures relating to Category III, published in the **Federal Register** of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. However, in view of the agency's determination that all OTC vaginal contraceptive drug products should be the subject of approved applications prior to marketing, interested parties can use that forum to meet with the agency to discuss appropriate testing procedures, and the comments do not need to be addressed in this document. Also, elsewhere in this issue of the **Federal Register**, the agency is announcing the availability of a guidance document that is intended to help manufacturers of vaginal contraceptive drug products develop data in support of new drug applications.

II. The Agency's Tentative Conclusions on OTC Vaginal Contraceptive Drug Products

Dodecaethyleneglycol monolaurate, laureth 10S, methoxypolyoxyethyleneglycol 550 laurate, nonoxynol 9, octoxynol 9, phenylmercuric acetate, and phenylmercuric nitrate have been present as ingredients in OTC vaginal contraceptive drug products. Based on the available evidence, the agency has determined that clinical studies in humans are necessary to establish the effectiveness of final formulations of vaginal contraceptive drug products and, therefore, any drug product that is labeled, represented, or promoted for use as a vaginal contraceptive is regarded as a new drug within the meaning of section 201(p) of the act (21 U.S.C. 321(p)), for which an approved application under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 of the regulations is required for marketing. In the absence of an approved application, such a product also would be misbranded under section 502 of the act (21 U.S.C. 352).

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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). 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 thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. There are a limited number of OTC vaginal contraceptive products that are not marketed for use with a condom, diaphragm, or contraceptive cervical cap. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC vaginal contraceptive drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC vaginal contraceptive drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on vaginal contraceptive drug products, a period of 120 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) 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.

In the **Federal Register** of December 12, 1980 (45 FR 82014 at 82047), the agency proposed that the monograph for OTC vaginal contraceptive drug products be included in subpart A of new part 351 of Title 21 of the Code of Federal Regulations. In the **Federal Register** of October 13, 1983 (48 FR 46694 at 46727), the agency proposed that a monograph for OTC vaginal drug products be included in subpart B of part 351. The current proposal supersedes subpart A of part 351 and, if finalized as proposed, Part 310—New Drugs would be amended to include OTC vaginal contraceptive drug products.

Interested persons may, on or before June 5, 1995 submit to the Dockets Management Branch written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before June 5, 1995. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before February 5, 1996, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before April 3, 1996. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations