ADDRESS: Requests for a copy of the petitions and written comments regarding the petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fisher Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Carol A. Kimbrough, Center for Drugs and Biologics (HFN-364), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8046.

SUPPLEMENTARY INFORMATION: On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984. This statute amends the Federal Food, Drug, and Cosmetic Act (the act) by authorizing the agency to accept abbreviated new drug applications (ANDA's) for most previously approved new drug products. This legislation also provides for extending the term of a patent which claims a product, use, or method of manufacture that was subject to a regulatory review period in accordance with the act. Further, the legislation provides for periods of exclusive marketing ("exclusivity") of certain new drug products approved in an application (or a supplement to an application) submitted under section 505(b) of the act (21 U.S.C. 355(b)). An ANDA or paper new drug application (NDA) for such a drug may not be submitted, under some provisions or made effective, under other provisions, until the period of exclusivity ends.

The new drug products that have been granted periods of exclusivity under one of the several exclusivity provisions of the 1984 legislation are identified in the volume entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) and its monthly supplements. For each such drug product, the period of exclusivity is shown. Further, the list shows those products that are covered by a patent and when the patent expires.

The agency believes that all patent and exclusivity information appearing in the list is correct, and expects that such information appearing in any future supplements to the list will also be correct. However, interested persons may disagree with the agency's findings and believe that FDA has excluded patent or exclusivity information that should have been included, or included patent or exclusivity information that should have been excluded. Accordingly, FDA has established a policy that, whenever an interested person submits a citizen petition requesting such inclusion or exclusion, the agency will publish a notice in the Federal Register of the avaliability of the petition. This publication is constructive notice to all interested persons that they may be affected by the petition and gives them an opportunity to submit their comments on the petition to the agency. Persons potentially affected include holders of approved ANDA's or approved paper NDA's the effective dates of which might be changed by a decision to grant the petition, persons who have pending ANDA's or paper NDA's or who contemplate submitting such applications that, when approved, would have effective dates that will be determined by the decision on the petition or, in some cases, persons whose right to submit such applications may be affected. Where a petition seeks a change in a decision to grant exclusivity, the applicant granted exclusivity has an obvious interest in the issue.

In accordance with FDA's policy, the agency is announcing the filing of two petitions in which Xttrium Laboratories seeks exclusivity for certain topical antimicrobial cleansing agents. Petition 86P-0186 requests exclusivity for an aerosol product and a solution product, each containing 4 percent chlorhexidine gluconate. Petition 86-0204 requests exclusivity for two solution products, one containing 2 percent chlorhexidine gluconate and the other containing 2.5 percent chlorhexidine gluconate. In each petition, Xttrium states that the glove juice studies and health care hand washing studies it was required to conduct were new clinical investigations meeting all the requirements for 3-year exclusivity under section 505(j)(4)(D)(iii) of the act.

FDA is reviewing the merits of these petitions and, by this notice, is giving anyone who may be affected by these petitions an opportunity to submit comments within 30 days.

Interested persons may, on or before July 21, 1986, submit to the Dockets Management Branch (address above) written comments on the petitions. These comments will be considered in preparing an agency response to the petitions. Two copies of any comments are to be submitted for each petition to which comments are addressed, except that individuals may submit one copy. Comments on the petition regarding the 4-percent chlorhexidine gluconate products should be identified with docket number 86P-0186 as shown in brackets in the heading of this document. Comments on the petition regarding the 2- and 2.5-percent chlorhexidine products should be identified with docket number 86P-0204 as shown in brackets in the heading of this document. Comments addressed to both petitions should be identified with both docket numbers. The petitions and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Requests for a single copy of either or both petitions should contain the appropriate docket number or numbers and be sent to the Dockets Management Branch.

Dated: June 16, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-13950 Filed 6-19-86; 8:45 am]

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[Docket No. 86F-0171]

Reynolds Metals Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Reynolds Metals Co. has filed a petition proposing that the food additive regulations by amended to provide for the safe use of *alpha*-tridecyl-*omega*-hydroxypoly(oxyethylene) phosphate; *alpha*-butyl-*omega*-hydroxypoly (oxyethylene)poly(oxypropylene), minimum molecular weight 1,000; and *alpha*-lauroyl-*amega*-hydroxypoly(oxyethylene) in the manufacture of metallic articles intended to contact food.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 6B3931) has been filed by Reynolds Metals Co., 2101 Reynet Rd., Richmond, VA 23237, proposing that § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) be amended to provide for the safe use of *alpha*-tridecyl-*omega*-hydroxypoly (oxyethylene) phosphate; *alpha-butyl-omega*-hydroxypoly(oxyethylene)-poly(oxypropylene), minimum molecular weight 1,000; and *alpha*-lauroyl-*omega*-hydroxypoly(oxyethylene) in the manufacture of metallic articles intended to contact food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and