Use of Ozone-Depleting Substances; Removal of Essential Use Designations; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of April 23, 2007, for the direct final rule that appeared in the Federal Register of December 7, 2006 (71 FR 70870). The direct final rule amends the regulation to remove beclomethasone, dexamethasone, fluticasone, bitolterol, salmeterol, ergotamine tartrate, and ipratropium bromide, used in oral pressurized metered-dose inhalers, from the list of essential uses of ozone-depleting substances. None of these products is currently being marketed. This document confirms the effective date of the direct final rule.


FOR FURTHER INFORMATION CONTACT: Martha Nguyen or 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: In the Federal Register of December 7, 2006 (71 FR 70870), FDA solicited comments concerning the direct final rule for a 75-day period ending February 20, 2007. FDA stated that the effective date of the
direct final rule would be on April 23, 2007, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period.

FDA received no significant adverse comments within the comment period. Therefore, under the Federal Food, Drug, and Cosmetic Act, the Clean Air Act, and under authority delegated to the Commissioner of Food and Drugs, after consultation with the Administrator of the Environmental Protection Agency, notice is given that no objections or requests for a hearing were filed in response to the December 7, 2006, direct final rule. Accordingly,
FDA is confirming that the amendment issued thereby is effective April 23, 2007, except for the removal of § 2.125(e)(4)(v), which is effective August 1, 2007.

Dated: 4/17/07
April 17, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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