



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. FDA-2015-N-1355]

RIN 0910-AH36

Use of Ozone-Depleting Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: In accordance with a determination by the Director of the Office of Management and Budget (OMB) that the direct final rule (“Use of Ozone Depleting Substances”) published on October 26, 2016, is excluded from the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” this action confirms the effective date of February 23, 2017, for the direct final rule.

DATES: The effective date of the direct final rule that published on October 26, 2016, at 81 FR 74298, is confirmed to be February 23, 2017.

FOR FURTHER INFORMATION CONTACT: Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6246, Silver Spring, MD 20993, 240-402-0979, daniel.orr@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On October 26, 2016, the Food and Drug Administration (FDA or Agency) issued a direct final rule amending the regulation on uses of ozone-depleting substances (ODSs), including chlorofluorocarbons, to remove the designations for sterile aerosol talc administered intrapleurally by thoracoscopy for human use and metered-

dose atropine sulfate aerosol human drugs administered by oral inhalation as “essential uses” under the Clean Air Act. FDA took this action because alternative products that do not use ODSs are now available, and because these products are no longer being marketed in versions that contain ODSs. FDA did not receive any significant adverse comments regarding the direct final rule, which was published with an effective date of February 23, 2017.

A memorandum of January 20, 2017 (82 FR 8346), from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” directed the heads of Executive Departments and Agencies to temporarily postpone for 60 days from the date of the memorandum the effective dates of all regulations that had been published in the Federal Register but had not yet taken effect, for the purpose of “reviewing questions of fact, law, and policy they raise.” The memorandum also stated that the Director of OMB may exclude certain regulations if they “affect critical health, safety, financial, or national security matters, or for some other reason.” Pursuant to the memorandum, the Director of OMB has excluded the direct final rule that published on October 26, 2016, at 81 FR 74298, from the directive to delay the effective date of certain regulations. The Department, therefore, confirms that the effective date of the direct final rule is February 23, 2017.

Dated: February 22, 2017

Thomas E. Price,
Secretary

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