FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and, therefore, that the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before October 15, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 173**

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

## PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by redesignating paragraph (e) as paragraph (f) and by adding new paragraph (e) to read as follows:

**§ 173.325 Acidified sodium chlorite solutions.**

* * * * *

(e) The additive is used as an antimicrobial agent on raw agricultural commodities in the preparing, packing, or holding of the food for commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, in accordance with current industry standards of good manufacturing practice. Applied as a dip or a spray, the additive is used at levels that result in chlorite concentrations of 500 to 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treatment of the raw agricultural commodities with acidified sodium chlorite solutions shall be followed by a potable water rinse, or by blanching, cooking, or canning.

* * * * *

Dated: September 8, 1999.

**L. Robert Lake,**

*Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.*

[FR Doc. 99–23969 Filed 9–14–99; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF JUSTICE

## 21 CFR Part 1308

**[DEA–182F]**

## Schedules of Controlled Substances: Placement of Zaleplon Into Schedule IV

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Final rule.

**SUMMARY:** With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance, zaleplon, including its salts, into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, importation and exportation of zaleplon and products containing zaleplon.

**EFFECTIVE DATE:** September 15, 1999.

**FOR FURTHER INFORMATION CONTACT:** Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

**SUPPLEMENTARY INFORMATION:** Zaleplon is a central nervous system (CNS) depressant that will be marketed under the trade name SONATA™ for the short-term treatment of insomnia.

On March 31, 1999, the Assistant Secretary for Health and Surgeon General, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA letter recommending that zaleplon, and its salts, be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the March 31, 1999, letter was a document prepared by the Food and Drug Administration (FDA) entitled ''Basis for the Recommendation for Control of Zaleplon in Schedule IV of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider [21 U.S.C. 811 (b)].

The correspondence from the Assistant Secretary for Health and Surgeon General to the DEA dated March 31, 1999, confirmed that FDA had determined that the New Drug Application (NDA) for zaleplon was ''approvable'' and had issued an approvable letter to the NDA sponsor on January 6, 1999. According to the March 31, 1999, letter from DHHS, ''upon full approval of the NDA, zaleplon will have a currently accepted medical use in treatment in the United States.''

After a review of the available data, including the DHHS recommendation,

the Deputy Administrator of the DEA, in a May 5, 1999, **Federal Register** Notice (63 FR 24094), proposed placement of zaleplon into Schedule IV of the CSA, if and when the zeleplon NDA is approved by the FDA. The notice provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing in writing to be received by the DEA on or before June 4, 1999. The DEA did not receive any comments regarding the proposal.

On August 16, 1999, the FDA notified the DEA that the zaleplon NDA was approved by the FDA on August 13, 1999. Relying on the scientific and medical evaluation and the recommendation of the DHHS Assistant Secretary for Health and Surgeon General received in accordance with section 201(b) of the Act [21 U.S.C. 811(b)], and the independent review of the DEA, the Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act [21 U.S.C. 811(a) and 811(b)], finds that:

(1) Based on information now available, zaleplon has a low potential for abuse relative to the drugs or other substances in Schedule III;

(2) Zaleplon has a currently accepted medical use in treatment in the United States; and

(3) Abuse of zaleplon may lead to limited physical dependence and psychological dependence relative to the drugs or other substances in Schedule III.

Based on these findings, the Deputy Administrator of the DEA concludes that zaleplon, including its salts, warrants control in Schedule IV of the CSA.

In order to make zaleplon pharmaceutical products available for medical use as soon as possible, the Schedule IV controls of zaleplon will be effective September 15, 1999. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule IV regulations regarding zaleplon. The applicable regulations are as follows:

1. Registration. Any person who manufactures, distributes, dispenses, imports or exports zaleplon or who engages in research or conducts instructional activities with zaleplon, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations.

2. Security. Zaleplon must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. Labeling and Packaging. All labels on commercial containers of, and all labeling of, zaleplon shall comply with the requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

4. Inventory. Registrants possessing zaleplon are required to take inventories pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations.

5. *Records.* All registrants must keep records pursuant to §§ 1304.03, 1304.04 and 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

6. *Prescriptions.* All prescriptions for zaleplon are to be issued pursuant to §§ 1306.03–1306.06 and 1306.21–1306.26 of Title 21 of the Code of Federal Regulations.

7. *Importation and Exportation.* All importation and exportation of zaleplon shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. *Criminal Liability.* Any activity with zaleplon not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful.

In accordance with the provisions of the CSA [21 U.S.C. 811(a)], this action is a formal rulemaking on the record after opportunity for a hearing. Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, Section 3(d)(1).

The Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C.. 605(b)], has reviewed this final rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. Zaleplon is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule IV of the CSA. This final rule will allow these entities to have access to a new pharmaceutical product.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Narcotics, Prescriptions drugs, Reporting and recordkeeping requirements.

Under the authority vested in the Attorney General by section 201(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

## PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by redesignating the existing paragraph (c)(48) to (c)(49) and by adding a new paragraph (c)(48) to read as follows:

**§ 1308.14 Schedule IV**

* * * * *

(c) * * *

(48) Zaleplon 2781

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Dated: September 7, 1999.

**Donnie R. Marshall,**

*Deputy Administrator.*

[FR Doc. 99–23968 Filed 9–14–99; 8:45 am]

BILLING CODE 4410–09–M