

displaces both State legislative requirements and State common law duties. We also note that even where the express preemption provision is not applicable, implied preemption may arise. See *Geier v. American Honda Co.*, 529 US 861 (2000).

FDA believes that the preemptive effect of the final rule would be consistent with Executive Order 13132. Section 4(e) of the Executive order provides that "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings." FDA provided the States with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the **Federal Register** of November 2, 2004 (69 FR 63482). FDA received no comments from any States on the proposed rulemaking.

In addition, on June 19, 2006, FDA's Division of Federal and State Relations provided notice via fax and email transmission to elected officials of State governments and their representatives of national organizations. The notice provided the States with further opportunity for comment on the rule. It advised the States of the publication of the proposed rule and encouraged State and local governments to review the notice and to provide any comments to Docket No. 1976N-0052N, opened in the November 2, 2004, **Federal Register** notice, by a date 30 days from the date of the notice (i.e., by July 19, 2006), or to contact certain named individuals. FDA received no comments in response to this notice. The notice has been filed in Docket No. 1976N-0052N.

In conclusion, FDA believes that it has complied with all of the applicable requirements under the Executive order and has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

X. Effective Date

This final rule becomes effective August 31, 2006.

XI. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 under Docket No. 1976N-0052N and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but is not responsible for

subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. *The United States Pharmacopeia 29-National Formulary 24*, The United States Pharmacopeial Convention, Inc., Rockville, MD, pp 3005, 2006.

2. *CDER Data Standards Manual* (see sections entitled "Tablet Effervescent" and "Granule Effervescent") at <http://www.fda.gov/cder/dsm/DRG/drg00201.htm>.

3. *The United States Pharmacopeia 28-National Formulary 23, Supplement 2*, The United States Pharmacopeial Convention, Inc., Rockville, MD, pp 3520, 2005.

List of Subjects in 21 CFR Part 341

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 341 is amended as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 341.3 is amended by adding paragraph (i) to read as follows:

§ 341.3 Definitions.

(i) *Effervescent dosage form.* A dosage form intended to be dissolved in water before administration. It contains, in addition to the active ingredient(s), mixtures of acids (citric acid, tartaric acid) and sodium bicarbonate, which release carbon dioxide when dissolved in water.

3. Section 341.20 is amended by adding paragraph (a) (4) to read as follows:

§ 341.20 Nasal decongestant active ingredients.

(a) (4) Phenylephrine bitartrate in an effervescent dosage form.

4. Section 341.80 is amended by revising the headings in paragraphs (c)(1)(i) and (c)(1)(ii), and by adding paragraph (d)(1)(iii) to read as follows:

§ 341.80 Labeling of nasal decongestant drug products.

(c) (1) *Oral nasal decongestants—(i) For products containing phenylephrine hydrochloride, pseudoephedrine*

*hydrochloride, pseudoephedrine sulfate, or phenylephrine bitartrate identified in § 341.20 (a)(1) through (a)(4) when labeled for adults. * * **

(ii) *For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, pseudoephedrine sulfate, or phenylephrine bitartrate identified in § 341.20 (a)(1) through (a)(4) when labeled for children under 12 years of age. * * **

(d) * * *

(1) * * *

(iii) *For products containing phenylephrine bitartrate identified in § 341.20(a)(4). Include information on the number of dosage units and the quantity of water the dosage units are to be dissolved in prior to administration as shown in the following table:*

Age ¹	Dose ¹
Adults and children 12 years of age and over	15.6 milligrams every 4 hours not to exceed 62.4 milligrams in 24 hours
Children 6 to under 12 years of age	7.8 milligrams every 4 hours not to exceed 31.2 milligrams in 24 hours
Children under 6 years of age	Ask a doctor

¹Headings are not required to appear in the product's labeling

5. Section 341.85 is amended by revising the headings in paragraphs (b)(2) and (b)(3).

§ 341.85 Labeling of permitted combinations of active ingredients.

(b) * * *

(2) *For permitted combinations containing an analgesic-antipyretic active ingredient identified in § 341.40 (a), (c), (f), (g), (m), (q), and (r) when labeled for relief of hay fever/allergic rhinitis and/or nasal congestion symptoms. * * **

(3) *For permitted combinations containing an oral analgesic-antipyretic active ingredient identified in § 341.40 (a), (c), (f), (g), (m), (q), and (r) when labeled for relief of general cough-cold symptoms and/or the common cold and for relief of hay fever/allergic rhinitis and/or nasal congestion symptoms. * * **