onerous. INGAA asserts the pipelines are still devoting considerable resources to ensure a smooth implementation of the first set of 140 standards being implemented April thru June. INGAA maintains that the GISB and the Commission schedule places the industry under too much time pressure, especially while the pipelines are attempting to finalize implementation during the period of uncertainty between final and rehearing orders. INGAA proposes that the schedule start with *pro forma* filings no later than November 1, 1997 with implementation no later than June 1, 1998.

INGAA maintains, however, that some pipelines may gain economic efficiency by implementing the 27 supplemental business practices standards early because these standards complement the first 140 standards. Thus, it emphasizes that its proposal is for implementation "no later than" the proposed dates.

CIG/WIC maintain that the August 1, 1997, deadline for implementation of the downloadable file format is unrealistic since GISB has not developed the standards yet. CIG/WIC find similarly unrealistic the September 1, 1997 deadline for clarification of the vague standards given the complexity of the issues.

Discussion

INGAA's request for an extension of the deadline for compliance with Order No. 587–C until June 1, 1998 is denied. The schedule proposed by GISB reflects a consensus of the industry as to an appropriate schedule for implementation, and the Commission finds no reason to delay implementation. Standardization of business practices and communications needs to be a high priority for the industry, and postponing implementation until the summer of 1998 would unduly delay these efforts.

INGAA has not identified any factors that would make implementation of these standards generally difficult for pipelines. There are only 27 revised and new business practices standards, and these merely supplement the previous 140 standards. Similarly, the technology for posting information on World Wide Web pages is easily available, and there are only five categories of information that must be posted. The absence of a generically applicable implementation problem is evidenced by INGAA's own recognition that many pipelines would prefer to implement these standards earlier than INGAA's proposed schedule for operational reasons. Indeed, some pipelines have sought to comply with all or most of the 27 supplemental standards six months early by including them (along with the first 140) in their final compliance filing to become effective June 1, 1997.[5]

Further, in Order No. 587–C, the Commission provided that any pipelines seeking waivers of the requirements of the rule file within 30 days of issuance.[6] To date, only five pipelines have filed for extensions of the implementation dates and two have filed to extend the tariff filing date, but not the implementation dates.[7] Handling specific problems on an individual basis is preferable to granting a generic extension and will result in more rapid progress towards the Commission's goal of reaching a standardized marketplace.

CIG/WIC's rehearing request concerning the August 1, 1997, deadline for pipelines to provide for downloads of data from their homepages is without basis. As pointed out above, the Commission did not adopt Standard 4.3.5 requiring pipelines to provide for file downloads; the Commission only expressed its intention should GISB act quickly. Until that standard is adopted and a deadline set, rehearing does not lie. The Commission, however, reiterates that the development of a file download capability is important and urges GISB to develop the required standards.

The Commission denies CIG/WIC's request for rehearing with respect to the September 1, 1997 date for GISB to report on its progress in resolving the three vague standards. This deadline also is necessary for the Commission to learn within a reasonable timeframe whether the industry can resolve these issues on its own or whether the Commission needs to institute procedures to resolve these disputes. If the industry is unable to reach agreement on these standards, postponing the deadline will only lead to even further delay in implementing these needed standards.

The September 1, 1997 deadline gives the industry five months to work on these standards, which appears adequate to consider these three standards. The imbalance and operational balancing agreement standards require only a clearer definition of when the standards apply.[8] Although, as CIG/WIC point out, the intra-day nomination issue is perhaps more complex, GISB has already appointed its own task force to examine this issue. Resolving this standard quickly also is imperative, since the existing intra-day requirements have created a non-standardized marketplace where shippers cannot coordinate their intra-day nominations across pipelines.[9] In addition, as the Commission stated in Order No. 587–C, it stands ready to help expedite the process by resolving intractable policy disputes impeding the development of standards in any areas.[10]

The Commission orders: The requests for rehearing are denied.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 97–10607 Filed 4–23–97; 8:45 am]

BILLING CODE 6717–01–P

[5] *See* Northwest Pipeline Company's compliance filing, Docket No. RP97–180–002 (April 1, 1997) (all 27 business practices standards and the World Wide Web standard); CNG Transmission Company's compliance filing, Docket No. RP97–181–002 (April 1, 1997) (22 business practices standards).

[6] 62 FR at 10689; III FERC Stats. & Regs. Regulations Preambles at 30,588.

[7] Tennessee Gas Pipeline Company, Docket No. RP97–60–001; Midwestern Gas Transmission Company, Docket No. RP97–59–001; East Tennessee Natural Gas Company, Docket No. RP97–58–001; Williston Basin Interstate Pipeline Company, Docket No. RM96–1–006; Cove Point LNG, L.P., Docket No. RP97–162–000; Questar Pipeline Company, Docket No. RP97–129–000; and Overthrust Pipeline Company, Docket No. RP97–131–000.

[8] These standards used the phrase "economically and operationally feasible" to describe when the pipeline must enter into an OBA and the phrase "substantially similar financial and operational implications" to describe when pipelines must permit shippers to net imbalances across contracts.

[9] 62 FR at 10687; III FERC Stats. & Regs. Regulations Preambles at ¶ 30,586.

[10] 62 FR at 10686; III FERC Stats. & Regs. Regulations Preambles at ¶ 30,583.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N–0309]

Drug Labeling; Sodium Labeling for Over-the-Counter Drugs; Partial Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is delaying the effective date of the sodium labeling final rule for over-the-counter (OTC) drug products intended for oral ingestion, except for those products that contain sodium bicarbonate, sodium phosphate, or sodium biphosphate as an active ingredient. The regulation established conditions under which the labeling must include the sodium

content and a general warning that persons who are on a sodium-restricted diet should not take the product unless directed by a doctor. This partial delay of the effective date of the sodium labeling final rule is in response to requests that the effective date for the sodium labeling final rule coincide with the effective date for the calcium, magnesium, and potassium labeling final rule. The final rule for calcium, magnesium, and potassium labeling is expected to publish in the **Federal Register** in the near future and will be effective 12 months after the date of publication. The agency is delaying the effective date of the sodium labeling final rule to correspond with the effective date of that final rule.

DATES: The effective date of paragraphs (a) through (h) of § 201.64 added at 61 FR 17806 (April 22, 1996) is delayed until further notice. The revision of paragraph (i) of § 201.64 in this document is effective April 24, 1997.

FOR FURTHER INFORMATION CONTACT: Ida Yoder, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 22, 1996 (61 FR 17798), FDA issued a final rule amending the general labeling provisions for OTC drug products (§ 201.64 (21 CFR 201.64)) to: (1) Require that the sodium content of all OTC drug products intended for oral ingestion be included in labeling when the product contains 5 milligrams (mg) or more sodium per a single dose; (2) require that all OTC drug products intended for oral ingestion containing more than 140 mg sodium in the labeled maximum daily dose bear a general warning that persons who are on a sodium-restricted diet should not take the product unless directed by a doctor; and (3) provide for the voluntary use of certain terms ("sodium free," "very low sodium," and "low sodium") relating to an OTC drug product's sodium content per labeled maximum daily dose. The effective date of the final rule is April 22, 1997. In the final rule, the agency also sought comments concerning whether the rule should be amended to include sodium content labeling for OTC rectal laxative, vaginal, dentifrice, mouthwash, and mouth rinse drug products. Interested persons were invited to submit comments by July 22, 1996. In response to two requests for extension of time to file comments to the final rule, FDA published a notice in the **Federal Register** of July 22, 1996 (61 FR 38046), extending the comment period until September 20, 1996.

In response to the final rule, comments were received from four manufacturers and two trade associations. Two of the comments requested that the effective date of the final rule be extended for at least an additional 6 months, to October 1997 or later. One comment mentioned the need for ongoing technical work, noting that manufacturers have undertaken formal product testing to ascertain precise sodium content before preparing new labels with accurate content declarations. The comment pointed out that the sodium content of inactive ingredients in products was a problem because specifications for some OTC drug ingredients do not include limits for sodium, suppliers often do not provide entire formulation information to companies, and sodium content may vary from lot to lot and/or supplier to supplier, especially for ingredients of natural origin. The comment stated that it would be difficult for some companies to complete product testing in time to have new labeling prepared by April 1997. The other comment stated that additional time would reduce label obsolescence, allow the use of already printed labeling, and allow labeling to be changed using current staff levels.

Both comments emphasized that FDA should delay implementation of the sodium labeling final rule until the proposed rule on labeling for OTC drug products containing calcium, magnesium, and potassium (61 FR 17807, April 22, 1996) was finalized. The comments contended that coordinating the effective date of both rules, which could apply to any single product, would avoid two label changes and the related economic impact of phasing in label changes for two separate rulemakings. One comment added that no major public health consequence should be expected from this delay for the sodium labeling because OTC drug products with relatively high sodium contents, e.g., antacids and laxatives, already bear a restricted sodium-use warning.

II. The Agency's Response to the Comments

FDA agrees with the comments' rationale that it is desirable to coordinate implementation of the sodium labeling with the calcium, magnesium, and potassium labeling. A single effective date for both final rules avoids two labeling changes and reduces the economic impact of phasing in labeling changes for two separate, but related, rulemakings. In addition, a short delay provides manufacturers additional time that should be sufficient to complete all product analyses. FDA notified all commentors of its intentions in a feedback letter (Ref. 1) and asked the Nonprescription Drug Manufacturers Association (NDMA) to notify its members and suggest that they incorporate calcium, magnesium, and potassium analyses into current plans to do sodium analyses so that all analyses can be completed and new labeling implemented by the effective date. FDA concurs with one comment that there should be no major public health consequences because of this short delay.

In the near future, FDA intends to publish, in the **Federal Register**, a final rule containing the labeling requirements for orally ingested OTC drug products containing calcium, magnesium, and potassium. That final rule will become effective 12 months after date of publication in the **Federal Register**. The final rule for sodium labeling will become effective on the same date.

For safety reasons, FDA is not delaying the effective date of the sodium labeling requirements for OTC drug products that contain sodium bicarbonate, sodium phosphate, or sodium biphosphate as an active ingredient. Section 201.64(i) of the sodium labeling final rule (61 FR 17798 at 17806) is effective April 22, 1997 for all OTC drug products intended for oral ingestion that contain sodium bicarbonate, sodium phosphate, or sodium biphosphate as an active ingredient. Accordingly, the agency is amending § 201.64(i) to reflect the effective date for these ingredients. The agency has already published notices of proposed rulemaking describing its concerns about these ingredients. See the **Federal Register** of February 2, 1994 (59 FR 5060), for sodium bicarbonate and the **Federal Register** of March 31, 1994 (59 FR 15139), for sodium phosphate and sodium biphosphate. The agency hopes to finalize those proposals in the near future.

III. Reference

The following reference has been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) Letter from D. Bowen, FDA, to L. Totman, NDMA, January 14, 1997, in Docket No. 90N–0309, Dockets Management Branch.

IV. Summary of Partial Delay of Effective Date

This final rule extends the effective date of the final rule for sodium labeling of OTC drugs for almost all OTC drug products for about 1 year, although the exact date is not known at this time. The effective date for the sodium labeling will coincide with the effective date for the calcium, magnesium, and potassium labeling. For safety reasons, FDA is not delaying the effective date of the sodium labeling requirements for OTC drug products that contain sodium bicarbonate, sodium phosphate, or sodium biphosphate as an active ingredient.

V. Analysis of Impacts

The economic impact of the sodium labeling regulation was discussed in the final rule (61 FR 17798 at 17805 and 17806). A delay in the effective date will provide additional time for companies to do product analyses and will reduce label obsolescence, as there will be additional time to use up more existing labeling. Thus, this final rule granting a partial delay of effective date should reduce the economic impact on industry.

FDA has examined the impacts of the final rule (partial delay of effective date) under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule provides a partial delay in the effective date. The delay in the effective date will provide manufacturers additional time to do product analyses and to use up existing product labeling. Thus, this final rule should reduce the economic impact on industry. Accordingly, the Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling is a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 510, 512, 530–542, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg–360ss, 371, 374, 379e); secs. 215, 301, 351, 361 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 264).

2. The effective date for § 201.64(a) through (h) that was added in the **Federal Register** of April 22, 1996 (61 FR 17798), is delayed until further notice and § 201.64(i) is revised to read as follows:

§ 201.64 Sodium labeling.

* * * * *

(i) Any product subject to this paragraph that contains sodium bicarbonate, sodium phosphate, or sodium biphosphate as an active ingredient for oral ingestion and that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after April 22, 1997, is misbranded under sections 201(n) and 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act (the act).

Dated: April 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–10595 Filed 4–21–97; 11:51 am]

BILLING CODE 4160–01–F

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Reinstatement of Exchange Visitors Unlawfully Present in the United States

AGENCY: United States Information Agency.

ACTION: Statement of agency policy.

SUMMARY: Pending a formal rulemaking, this Statement of Agency Policy sets forth the circumstances under which the Agency will reinstate an exchange visitor (J Visa) who is unlawfully present in the United States.

DATES: This statement of Agency policy is effective April 24, 1997.

ADDRESS: United States Information Agency, Office of the General Counsel, 301 Fourth Street, SW, Room 700, Washington, DC 20547–0001.

FOR FURTHER INFORMATION CONTACT: Exchange Visitor Program Office, United States Information Agency, 301 Fourth Street, S.W., Washington, DC 20547; telephone (202) 401–9810.

SUPPLEMENTARY INFORMATION: Section 632 ("Elimination of Consulate Shopping for Visa Overstays") of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (Public Law 104–208) (IIRAIRA) amended Section 222 of the Immigration and Nationality Act by adding a new paragraph "(g)." That new paragraph, in pertinent part, provides that an alien who has been admitted on the basis of a nonimmigrant visa and "remained in the United States beyond the period of stay authorized by the Attorney General, such visa shall be void beginning after the conclusion of such period of stay." An alien who remained in the United States beyond the period of stay authorized by the Attorney General is ineligible for readmission to the United States on the previously issued nonimmigrant visa. The alien must have a new visa issued after the overstay violation from a consular office in the alien's country of nationality or, where extraordinary circumstances are found to exist, at a consular office outside the alien's country of nationality.