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.

The Immigration and Naturalization Service (INS) has provided interim guidelines with respect to the above-described section. Those guidelines construe the terms ''beyond the period of stay authorized'' to mean past the date entered for departure on a nonimmigrant's Form I–94. For J visa nonimmigrants whose Form I–94 authorizes admission for ''Duration of Status'' (D/S), the ''period of stay authorized'' ends on the date of expiration of the 30 day grace period after the alien completes, concludes, ceases, interrupts, graduates from or otherwise terminates his or her course of study or exchange program.

The Illegal Immigration Reform and Immigrant Responsibility Act of 1996 contains another provision which affects nonimmigrants who remain in the United States beyond the period of stay authorized. Section 301 of that Act deems an alien to be ''unlawfully present in the United States'' if the alien is present in the United States after the expiration of the period of stay authorized by the Attorney General. If the alien was unlawfully present in the United States for a period of 180 days but less than one year, voluntarily departed the United States prior to the commencement of removal proceedings, and again seeks admission to the United States, the alien is inadmissible for three years from the date of departure. If the alien was unlawfully present in the United States for one year or more, and again seeks admission, the alien is inadmissible for 10 years from the date of departure or removal from the United States.

The effective date of Section 301 of IIRAIRA is April 1, 1997. Section 632 became effective on September 30, 1996.

Because the above two sections of the Act may have serious repercussions for aliens who become ''unlawfully present in the United States,'' depart the United States, and then subsequently seek readmission to the United States, it obviously behooves such aliens to timely depart the United States on or before the end of the authorized period of stay or apply to extend their status if regulations permit.

The current Exchange Visitor Program regulations permit a Responsible Officer to extend an exchange visitor's participation in the program up to the limit of the permissible period of participation authorized for his or her specific program category. When this occurs, the Responsible Officer issues to the exchange visitor a duly authorized Form IAP–66 reflecting such extension and provides a notification copy of such form to the Agency. [22 CFR 514.43 (a) and (b).] Where the exchange visitor seeks an extension in excess of the period of time authorized for his or her specific category of participation, the Responsible Officer is required to notify USIA and seek prior written approval for such extension. [See 22 CFR 514.43(c) and 514.20(j)(2)(i).]

While it is not the responsibility of the sponsor to ensure that the exchange visitor timely departs the U.S., the Exchange Visitor Program regulations do require that a sponsor monitor its participating exchange visitors [22 CFR 514.10(e).] Among other things, the sponsor shall ensure that the activity in which the exchange visitor is engaged is consistent with the category and activity listed on the exchange visitor's Form IAP–66 [22 CFR 514.10(e)(1)]. The sponsor is also required to monitor the progress and welfare of the exchange visitor to the extent appropriate for the category [22 CFR 514.10(e)(2)]. Finally, the sponsor shall require the exchange visitor to keep the sponsor apprised of his or her address and telephone number, and maintain such information [22 CFR 514.10(e)(3)].

The Agency believes that the monitoring requirements set forth in the existing Exchange Visitor Program regulations implicitly require the sponsor to monitor the exchange visitor's Form IAP–66 to ensure that such form accurately reflects the activities and the program dates of the exchange visitor and that the exchange visitor is advised of the limitations on his or her activities and authorized stay in the United States. (Existing regulations also explicitly require the sponsor to notify the Agency in writing when the exchange visitor has withdrawn from or completed a program thirty or more days prior to the ending date on his or her Form IAP–66 or when the exchange visitor has been terminated from his or her program [22 CFR 514.13(c)].) Moreover, IIRAIRA implicitly requires the exchange visitor to monitor his or her status.

The Agency acknowledges that most program participants do not knowingly or willfully engage in practices that would jeopardize their status in the United States. However, the Agency is aware that on occasion, whether through circumstances beyond the control of the exchange visitor or through administrative oversight, inadvertence, or neglect on the part of a Responsible Officer or an exchange visitor, or both, the exchange visitor may become ''unlawfully present in the United States.'' The Exchange Visitor Program regulations are silent with respect to the issue of whether a Responsible Officer is authorized to reinstate an exchange visitor who is in the United States ''beyond the period of stay authorized by the Attorney General.''

After a careful review of Sections 301 and 632 of IIRIRA and working in consultation with the Immigration and Naturalization Service, the Agency has concluded that a Responsible Officer is not authorized to reinstate, *nunc pro tunc,* an exchange visitor once the exchange visitor is in the United States beyond the period of stay authorized by the Attorney General. Indeed, new section 222(g) of the Immigration and Nationality Act states ''such visa shall be void beginning after the conclusion of such period of stay.''

However, the Agency, in consultation with the Immigration and Naturalization Service, has concluded that under the authority conferred on the Director of USIA pursuant to Section 101(a)(15)(J) of the Immigration and Nationality Act, as amended [8 U.S.C. 1101(a)(15)(J)], the Mutual Educational and Cultural Exchange Act of 1961, as amended (22 U.S.C. 2451, *et seq.*,) and Reorganization Plan No. 2 of 1977, the Agency does have the authority to reinstate to lawful status an exchange visitor who remains in the United States beyond the period of stay authorized by the Attorney General and who thereby has become ''unlawfully present in the United States.'' As noted above, in the case of J visa immigrants whose Form I–94 authorized admission for Duration of Status, the period of stay authorized by the Attorney General ends on the date of expiration of the 30 day grace period after the exchange visitor completes, concludes, ceases, interrupts, graduates from or otherwise terminates his or her course of study or exchange program.

The Agency is therefore promulgating this statement of policy as a preliminary and interim measure, which will be followed by the Agency until a formal rulemaking is published. During this interim period, it will be Agency policy that the Agency will consider reinstating to lawful status a J–1 exchange visitor who makes a request for reinstatement through his or her Responsible Officer. In such cases, the Responsible Officer is to direct a letter to the Exchange Visitor Program Services office explaining that the violation of status resulted from circumstances beyond the control of the exchange visitor or from administrative oversight, inadvertence, or neglect on the part of the Responsible Officer or the exchange visitor and that failure to receive reinstatement to lawful status would result in unwarranted hardship to the exchange visitor. The letter is to contain a declaration that the exchange visitor is pursuing the exchange

program activity for which he or she was admitted to the United States.

The request for reinstatement also is to include copies of all of the exchange visitor's Forms IAP–66 issued to date and a new complete Form IAP–66 which indicates the date to which reinstatement is sought (namely, the program end date.) If the Agency determines that reinstatement is warranted, Box 6 on the new Form IAP–66 will be stamped by the Agency to indicate that reinstatement has been granted, effective as of the date that the request for reinstatement was received by the Agency. The new Form IAP–66 (minus the yellow copy) will be returned to the Responsible Officer. If the Agency does not approve the request for reinstatement the time for which the application was under review will count toward unauthorized status.

For purposes of Section 212(a)(9)(B) of the Immigration and Nationality Act (as amended by Section 301(b) of IIRAIRA), if the Agency approves the reinstatement, the calculation of the period of time specified in paragraph (B) will be tolled as of the date the request for reinstatement is received by the Agency. The Agency will deal expeditiously with all applications, and it is expected that most can be handled on a pro forma basis.

There are certain issues that this statement of policy purposely does not address. For example, if an exchange visitor wilfully fails to maintain the health and accident insurance required under 22 CFR 514.14, that exchange visitor is in violation of the regulations and is subject to being terminated from the exchange visitor program. (22 CFR 514.14 (h) and (i)). An exchange visitor terminated from the exchange visitor program for wilfull failure to maintain health and accident insurance is not eligible for reinstatement.

Nor are employment-related issues dealt with in this statement of policy. Any exchange visitor who engages in unauthorized employment is subject to termination by the sponsor. Existing regulations require the sponsor to ensure that the activity in which the exchange visitor is engaged is consistent with the category and activity listed on the exchange visitor's Form IAP–66 (22 CFR 514.10(e)(1); 514.40.) An exchange visitor who is terminated from participation in his or her exchange program for unauthorized employment is not eligible for reinstatement.

Thus, while an exchange visitor may be in violation of the Agency's regulations regarding insurance coverage or employment, such violations would not in and of themselves make the exchange visitor ''unlawfully present in the United States'' within the meaning of IIRIRA. Those violations shall be dealt with under the existing Exchange Visitor Program regulations, and if the exchange visitor is terminated from the exchange program for such violations, he or she is ineligible for reinstatement.

The Agency anticipates that a Proposed Final Rule will be published in the **Federal Register** by July 1, 1997. Interested parties will have an opportunity to comment in writing on the proposed rule.

Dated: April 18, 1997.

Les Jin,

General Counsel.

[FR Doc. 97–10613 Filed 4–23–97; 8:45 am]

BILLING CODE 8230–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 151

Land Acquisitions

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of final agency determination to take land into trust.

SUMMARY: The Assistant Secretary—Indian Affairs made a final agency determination to acquire approximately 480.32 acres, more or less, of land into trust for the Saginaw Chippewa Indian Tribe of Michigan on April 14, 1997. This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

DATES: This determination is effective April 14, 1997.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, MS 2070–MIB, 1849 C Street NW, Washington, D.C. 20240, telephone (202) 219–4066.

SUPPLEMENTARY INFORMATION: This notice is published to comply with the requirement of 25 CFR 151.12(b) that notice be given to the public of the Secretary's decision to acquire land in trust at least 30 days prior to signatory acceptance of the land into trust. The purpose of the 30-day waiting period in 25 CFR 151.12(b) is to afford interested parties the opportunity to seek judicial review of final administrative decisions to take land in trust for Indian tribes and individual Indians before transfer of title to the property occurs. On April 14, 1997, the Assistant Secretary—Indian Affairs decided to accept approximately 480.32 acres, more or less, of land into trust for the Saginaw Chippewa Indian Tribe of Michigan pursuant to the Indian Reorganization Act (IRA) of June 18, 1934, (48 Stat. 884; 25 U.S.C. 465). The Secretary shall acquire title in the name of the United States in trust for the Saginaw Chippewa Indian Tribe of Michigan for the following parcels of land described below no sooner than 30 days after the date of this notice.

A parcel of land being part of the N½ of Section 18, T14N, R3W, described as beginning at a point on the E–W¼ line of said Section which is East 2281.0 feet from the W¼ corner of said Section thence N 0°07′ E, 2382.19 feet; thence S 89°42′45″ E, 969.86 feet; thence S 0°08′08″ W, 175.22 feet; thence S 89°43′52″ E, 266.42 feet; thence S 0°08′08″ W, 2201.12 feet; thence N 89°59′ W, 932.84 feet along the E–W¼ line to the interior ¼ corner of said Section; thence West 302.56 feet along said E–W¼ line to the point of beginning; EXCEPT a part of the SW¼ of the NE¼ of Section 18, T14N, R3W, described as beginning at a point on the E–W¼ line of said Section which is S 89°59′ E, 150.0 feet from the Interior ¼ corner, thence N 0°07′ E, 450 feet, thence S 89°59′ E, 425 feet, thence S 0°07′ W, 450 feet, thence N 89°59′ W, 425 feet to the point of beginning, Chippewa Township, and

Part of the NW¼ of Section 18, T14N, R3W, described as beginning at a point on the West Section line which is N 0°23′50″ W, 208.7 feet from the W¼ corner of Section 18; thence N 0° 23′50″ W, 1011.3 feet; thence N 89°29′10″ E, 1625.0 feet parallel with the E–W¼ line; thence S 0°23′50″ E, 873.5 feet; thence S 89°29′10″ W, 377.15 feet; thence S 0°23′50″ E, 137.8 feet; thence S 89°29′10″ W, 1247.85 feet to the point of beginning, Chippewa Township, AND

A parcel of land being part of the NW¼ of Section 18, T14N, R3W, described as beginning at a point on the West line of Section 18 which is North 1220.0 feet from the W¼ corner of Section 18; thence North 680.07 feet along the West Section line; thence East 495.0 feet parallel with the E–W¼ line of Section 18; thence North 483.3 feet parallel with the West Section line to a point which is 165.0 feet South of the South right of way line of M–20 (Pickard Road); thence East 1386.0 feet parallel with the South right of way line of M–20; thence South 1164.19 feet parallel with the West Section line; thence West 1881.0 feet parallel with the E–W¼ line of Section 18, to the point of beginning, Chippewa Township, AND