juice content of diluted juice beverages. The agency has also received comments from several members of the U.S. Senate requesting that the comment period not be extended further. The agency has considered both viewpoints and believes that the data being obtained by CSPI are relevant to the evaluation of the proposal but that an additional 45 days beyond December 13, 1987, the current closing date for comments, should be sufficient. Accordingly, the agency is reopening the comment period for that additional length of time.

Interested persons may, on or before January 27, 1988, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 20, 1988.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-1355 Filed 1-20-88; 12:33 pm]

BILLING CODE 4160-01-M

21 CFR Part 201

[Docket No. 87N-0371]

Labeling for Oral and Rectal Over-the-Counter Aspirin and Aspirin-Containing Drug Products; Reye Syndrome Warning

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations that require the labeling of oral and rectal over-the-counter preparations containing aspirin to bear a Reye syndrome warning by deleting the provision that the regulation shall expire on June 6, 1988, unless extended by FDA. The agency is proposing that this labeling provision be made permanent. This action is based on the results of a study by the Public Health Service Reye Syndrome Task Force and the report of the Institute of Medicine's Committee on Reye Syndrome and Medication Use which confirm the association between Reye syndrome and the ingestion of aspirin and aspirin-containing drug products.

DATE: Comments by March 22, 1988.

ADDRESS: Written comments to the Docket Management Branch (HFA-305), Food and Drug Administration, 5600 Fishers Lane, Room 4-62, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug Evaluation and Research (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8046.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 17, 1985 (50 FR 51400), FDA proposed to require that the labeling of oral over-the-counter (OTC) aspirin and aspirin-containing drug products for human use bear a warning that such products should not be used to treat chicken pox or flu symptoms in children and teenagers before consulting a doctor about Reye syndrome. FDA proposed this rule in order to bring uniformity and consistency to the labeling of aspirin and aspirin-containing products in the marketplace and to aid in increasing the public awareness of the apparent association between the use of aspirin and Reye syndrome.

In the December 17, 1985, proposal, FDA described the scientific studies that had been conducted to examine the possible association between the use of aspirin and the occurrence of Reye syndrome. The agency noted that the Public Health Service (PHS) planned further research into the possible assciation between Reye snydrome and various exposure factors, including the use of aspirin.

The main PHS study, conducted under the direction of the PHS Reye Syndrome Task Force from 1984 to 1986, was preceded by a pilot phase (methodology study) to determine the study feasibility and to establish the appropriate methodology for a full-scale investigation. The methodology study, which is summarized in the December 17, 1985, proposal (50 FR 51401), reported an association between the use of aspirin and the occurrence of Reye syndrome in children and teenagers.

In the **Federal Register** of March 7, 1986 (51 FR 8180), FDA published a final regulation requiring the following labeling statement on orally or rectally administered OTC aspirin and aspirin-containing drug products: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness."

In addition to certain other provisions, the final rule required that this warning precede any additional warnings that may appear on the product labeling in order to assure the prominence of the message.

The final rule also included the provision that the regulation would expire 2 years from the effective date unless the agency acted to extend it. This 2-year period was to allow completion and evaluation of the PHS main study noted above.

The PHS main study has now been completed. The study results provide convincing evidence of a strong association between Reye syndrome and the ingestion of aspirin. The PHS report, entitled "Reye Syndrome and Medications—Report of the Main Study," was prepared by the PHS Reye Syndrome Task Force and is dated November 12, 1986 (Ref. 1). The PHS report was evaluated by the Institute of Medicine (IOM) of the National Academy of Sciences in a separate report dated February 1987, and entitiled "This PHS Study of the Reye Syndrome: Review of a Continuing Study—Report Number 6—Review of the PHS Continuing Study by the Committee on the Reye Syndrome and Medications." (Ref. 2) A report of the main PHS study was published in the *Journal of the American Medical Association* on April 10, 1987 (Ref. 3). These reports have been placed on display with the Dockets Management Branch (address above) under Docket No. 87N-0371. Additional background information may be found in Docket Nos. 82N-0158 and 85N-0553.

The PHS study findings reported a large, statistically significant association between Reye syndome and the ingestion of aspirin during previous illnesses. The study concluded that the association between Reye syndrome and aspirin is consistent with estimates of risk determined in earlier studies and reflects the strength of the epidemiologic association observed in those studies. The study reinforced the importance of reducing the use of aspirin in the treatment of children and teenagers with chicken pox and flu-like illness.

Because of the evidence developed from the PHS study and the evaulation of that study by the IOM of the National Academy of Sciences, FDA proposed that the warning statement in the labeling of orally or rectally administered OTC aspirin and aspirin-containing drug products be a permanant requirement. The available evidence supports the continuing need to maintain a high level of public awareness of the association between the use of aspirin in children and teenagers and the incidence of Reye syndrome; continuation of the requirement for the warning in the labeling of over-the-counter aspirin and aspirin-containing drug products will contribute to this goal. Therefore, the

agency is proposing to amend § 201.314 of the regulations (21 CFR 201.314) by removing paragraph (h)(5), thereby removing the expiration date of the labeling requirement.

The agency is aware that some interested individual may have questions about the precise wording of the warning statement or other aspects of the rule (Ref. 4). The agency believes that it is of the utmost importance that there be no time gap in requiring a Reye syndrome warning statement on aspirin and aspirin containing products. This proposal, therfore, is focused on extending the current warning statement. The agency will, of course, consider comments on related issues as part of the rulemaking process.

Economic Impact

FDA has examined the regulatory impact and regulatory flexibility implications of the proposed rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act. The proposal would simply require the continued use of labeling already prepared under the March 1986 final rule. Thus, no additional costs associated with labeling changes would result from this proposed rule. Therefore, the agency has determined that the proposed rule is not a major rule as defined in Executive Order 12291. Further, FDA certifies that the proposed rule will not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) 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.

References

The following information has been placed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

(1) "Reye Syndrome and Medications—Report of the Main Study," Public Health Service Reye Syndrome Task Force, November 12, 1986.

(2) "The PHS Study of the Reye Syndrome: Review of a Continuing Study—Report Number 6—Review of the PHS Continuing Study by the Committee on the Reye Syndrome and Medications," Institute of Medicine of the National Academy of Sciences February 1987.

(3) Hurwitz, E.S., et al., "Public Health Service Study of Reye's Syndrome and Medications, Report of the Main Study," *Journal of the American Medical Association*, 257(14):1905-1911, 1987.

(4) Letter from Richard M. Narkewicz, President, American Academy of Pediatrics, to Frank E. Young, Commissioner, FDA, dated November 13, 1987.

Comments

Interested persons may, on or before March 22, 1988, submit to the Docket Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 201

Drugs, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 201 be amended as follows:

PART 201—LABELING

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

Authority: Secs. 501, 502, 701, 52 Stat. 1049-1051 as amended (21 U.S.C. 351, 352, 371); 5 CFR 5.10; § 201.21 also issued under secs. 301, 505, 52 Stat. 1042-1043 as amended, 1052-1053 as amended (21 U.S.C. 331, 355).

§ 201.314 [Amended]

2. Section 201.314 *Labeling of drug preparations containing salicylates* is amended by removing paragraph (h)(5).

Dated: December 16, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-1200 Filed 1-21-88; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 151

Land Acquisitions

January 6, 1988

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule; withdrawal.

SUMMARY: On Tuesday, June 23, 1987, the Bureau of Indian Affairs published a proposed rule in the **Federal Register** (52 FR 23560) concerning the acquisition in trust status of lands located outside the boundaries of Indian reservations. The proposed rule would have amended 25 CFR Part 151, Land Acquisitions, by adding a new section (c) to 25 CFR 151.3. The new rule would have had the effect of prohibiting all acquisitions of off-reservation lands in trust status for Indian tribes and individuals if the proposed purpose of the acquisition was to establish a bingo operation or gaming enterprise.

A public comment period on the rule was given from June 23 to August 7, 1987. In general, comments received were overwhelmingly in opposition to the rule. A total of 30 responses were received, 25 from various Indian tribes and tribal attorneys who felt that such a regulation would be an "unwarranted constraint on economic development" and would be in direct contravention of the Federal policy of self-determination and self-sufficiency through economic development.

Additional concerns expressed by the tribes were that such a provision would be "overregulation" and, in light of future budget reductions, the Bureau would be depriving tribes of a legitimate economic enterprise. Of the five remaining responses which supported the proposed provision, three were from various horse racing associations, one from county officials in California, and the fifth from the Law Enforcement Branch of the Bureau of Indian Affairs' Billings Area Office.

Upon reconsideration, the Assistant Secretary finds that the proposed rule is not warranted at this time and hereby formally withdraws the rulemaking action. The Assistant Secretary further finds that, in unique instances, a bingo enterprise, even though established on trust land outside the reservation boundaries, may be essential to the economic well being of a tribe which has a very limited natural or financial resource base. Off-reservation land acquisition requests for bingo enterprises will continue to be considered on a case-by-case basis purusant to the existing guidelines found in 25 CFR Part 151.

This notice of proposed rule withdrawal is published in exercise of the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

EFFECTIVE DATE: The effective date of withdrawal is January 22, 1988.

FOR FURTHER INFORMATION CONTACT: Mr. Lee Maytubby on (202) 343-3837; U.S. Department of the Interior, Bureau of Indian Affairs, Division of Real Estate Services, Room 4520—Main Interior, 18th & C Streets NW., Washington, DC 20240, or Mr. Michael Cox on (202)