clarifying one and does not involve any label changes.

In accordance with the Regulatory Flexibility Act (Pub. L. 96–354 (5 U.S.C. 601)), FDA has considered the effect this proposed rule would have on small entities including small businesses. The proposed regulation clarifies the U.S. standard of identity for canned pineapple in response to an objection to a final regulation. The agency believes that the proposed regulation will not impose an additional burden on the industry. FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

The agency has determined under 21 CFR 25.24(b)(13) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 145

Canned fruits, Food standards, Fruits.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Part 145 be amended in § 145.180 by revising paragraph (a)(2)(vii) to read as follows:

PART 145—CANNED FRUITS

§ 145.180 Canned pineapple.

(a) * * *

(2) * * *

(vii) *Chunks*—consisting of short, thick pieces cut from thick slices and/or from peeled cored pineapple and predominantly more than 13 millimeters (0.51 inch) in both thickness and width, and less than 38 millimeters (1.5 inches) in length and does not include large cubes.

* * * * *

Interested persons may, on or before February 8, 1983 submit to the Docket Managment 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: December 6, 1982

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–33662 Filed 12–9–82; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 310

[Docket No. 80N–0419]

Aphrodisiac Drug Products for Over-the-Counter Human Use

Correction

In FR Doc. 82–27055, beginning on page 43572, on Friday, October 1, 1982, on page 43574, in the first column, in the second paragraph, in the twelfth line, "deficiency, specific" should read "deficiency, the administration of androgens is a highly effective specific".

BILLING CODE 1505–01–M

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21 CFR Part 357

[Docket No. 82N–0166]

Orally Administered Drug Products for Relief of Symptoms Associated With Overindulgence in Alcohol and Food for Over-the-Counter Human Use; Establishment of a Monograph

Correction

In FR Doc. 82–27054, beginning on page 43540, on Friday, October 1, 1982, make the following corrections:

1. On page 43549, in the second column, in the first line, "625 families" should read "626 families".

2. On page 43552, in the third column, in the second line "served," should read "severed,"

3. On page 43553, in the first column, in the second paragraph, in the fourteenth line, "July 8, 1077" should read "July 8, 1977".

BILLING CODE 1505–01–M

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21 CFR Part 886

[Docket No. 82N–0180]

Proposed Reclassification of Daily Wear Spherical Contact Lenses Consisting of Rigid Gas Permeable Plastic Materials; Extension of Time for Comment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; Extension of time for comment.

SUMMARY: The Food and Drug Administration (FDA) is extending the time within which interested persons may submit written comments on its proposal to reclassify marketed daily wear spherical contact lenses consisting of certain rigid gas permeable plastic materials from class III (premarket approval) into class I (general controls).

DATE: Comments by January 26, 1983.

ADDRESS: Written comments on the reclassification proposal may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Maria E. Donawa, National Center for Devices and Radiological Health (HFK–300), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7175.

SUPPLEMENTARY INFORMATION: FDA published the proposed rule in the **Federal Register** of November 26, 1982 (47 FR 53402), and gave 30 days for interested persons to submit written comments on the document to the agency. In accordance with section 520(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(d)(2)), which requires the agency to provide at least 60 days for interested persons to comment on any proposed rulemaking under section 513 of the act (21 U.S.C. 360c), FDA is extending the period of time for submission of comments to January 26, 1983.

Interested persons may, on or before January 26, 1983 submit to the Dockets Management Branch (address above), written comments regarding the reclassification 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: December 3, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–33659 Filed 12–9–82; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 886

[Docket No. 82N–0179]

Proposed Reclassification of Daily Wear Optically Spherical Hydrogel (Soft) Contact Lenses; Extension of Time for Comments

AGENCY: Food and Drug Administration.