the execution and clearance of the Nikkei futures contract and options thereon traded on the CME or the TOPIX futures contract and options thereon traded on the CBOT. Applicant asserts that these proposed activities are functionally similar to activities previously approved by the Board. *See, e.g., The HongKong and Shanghai Banking Corporation*, 76 Federal Reserve Bulletin 770 (1990)(Nikkei futures contract traded on the SIMEX; TOPIX futures contract traded on the TSE); *Chemical Banking Corporation, supra*. In conducting these activities, Applicant states that Company would comply with the commitments set forth in §§ 225.25(b)(18) and (19) of the Board's Regulation Y (12 CFR 225.25(b)(18), (19)), as well as the prudential limitations established by the Board in previous Orders. Accordingly, Applicant contends that the proposed activities are functionally similar to those currently being conducted by banks and bank holding companies and are therefore closely related to banking.

Applicant takes the position that the proposed activities will benefit the public. Applicant believes that the proposed activities will promote competition and provide added convenience to customers of Company and gains in efficiency. Moreover, Applicant believes that these benefits will outweigh any possible adverse effects of the proposed activities and that, indeed, no adverse effects are currently foreseen.

Any views or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC, 20551, not later than February 19, 1992. Any request for a hearing must, as required by § 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how that party commenting would be aggrieved by approval of the proposal.

This application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of San Francisco.

Board of Governors of the Federal Reserve System, January 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-2733 Filed 2-4-92; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 88N-0003]

RIN 0905-AA06

Antacid and Acetaminophen Combination Drug Products in a Solid Dosage Form; Marketing Status for Over-the-Counter Human Use; Notice of Enforcement Policy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an enforcement policy allowing over-the-counter (OTC) marketing of antacid and acetaminophen combination drug products in solid oral dosage forms. The OTC marketing of such drug products is being permitted pending establishment under the OTC drug review of an amendment to the final monograph for OTC antacid drug products. FDA anticipates that antacid and acetaminophen combination products in a solid oral dosage form will be determined to be generally recognized as safe and effective and not misbranded.

EFFECTIVE DATE: The enforcement policy is effective February 5, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1974 (39 FR 19862), FDA issued a final monograph for OTC antacid drug products (21 CFR part 331). Section 331.15(b) (21 CFR 331.15(b)) of the monograph provides for the combination of an antacid and any generally recognized as safe and effective analgesic ingredient(s), if the combination is indicated for use solely for concurrent symptoms, e.g., headache and acid indigestion, and is marketed in a form intended for ingestion as a solution. These combinations were limited to administration in solution because all the evidence of safety submitted for review under the rulemaking for OTC antacid drug products was derived from studies and experience with products administered as solutions (39 FR 19862 at 19869).

Subsequent to the publication of the final rule for OTC antacid drug products, the Advisory Review Panel for OTC Internal Analgesic and Antirheumatic Drug Products (the Internal Analgesic Panel) reviewed data on OTC antacid/analgesic combinations and recommended conditions for their safe and effective use in its report on OTC internal analgesic, antipyretic, and antirheumatic drug products (42 FR 35346, July 8, 1977). This Panel recommended that acetaminophen could be combined with a Category I antacid ingredient provided the product was labeled for the concurrent symptoms involved, e.g., "For the temporary relief of occasional minor aches, pains, and headache, * * *, and for acid indigestion." The Panel did not specify any specific dosage form.

In the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, published in the **Federal Register** of November 16, 1988 (53 FR 46204), FDA proposed that acetaminophen may be combined with any antacid ingredient(s) and may be labeled only for concurrent symptoms (see § 343.20(b)(1), 53 FR 46204 at 46255). In the same issue of the **Federal Register** (53 FR 46190), FDA also published a notice of proposed rulemaking to amend the final monograph for OTC antacid drug products to revise the conditions for marketing combination antacid/analgesic drug products. The agency proposed to update the antacid final monograph to be consistent with the proposals being made in part 343 (the internal analgesic, antipyretic, and antirheumatic tentative final monograph) to allow: (1) Antacid and acetaminophen ingredients to be combined and labeled only for concurrent symptoms, and (2) aspirin and antacid ingredients when marketed in a form intended for ingestion as a solution to be combined and labeled for concurrent symptoms as well as analgesic indications alone. The agency also stated that because of the interrelationship of the amendment to the antacid final monograph and the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, the agency did not intend to finalize the amendment to the antacid monograph until the comments to the internal analgesic, antipyretic, and antirheumatic tentative final monograph have been fully evaluated. Interested persons were given until March 16, 1989 to submit comments or objections to the proposal to amend the antacid monograph. No comments or objections were received.

After carefully reviewing all of the available information regarding antacid-acetaminophen combination drug products, the agency is issuing a notice of enforcement policy permitting OTC marketing of these drug products in a solid oral dosage form, a new dosage form that has not previously been marketed. The agency has determined that there are no unresolved safety or effectiveness issues relating to the OTC use of antacid-acetaminophen combination drug products in a solid oral dosage form. Accordingly, the agency finds no reason to continue to bar the interim marketing of such products.

As noted above, the November 16, 1988 proposed amendment of the antacid monograph also addressed aspirin and antacid combinations in a form intended for ingestion as a solution. Such combination drug products are presently being marketed. Therefore, it is not necessary to address their marketing status in this notice.

The agency advises that any antacid ingredient in § 331.11 (21 CFR 331.11) may be combined with acetaminophen in a solid oral dosage form (in accord with proposed § 343.20(b)(1) (53 FR 46204 at 46255)) provided the product is intended and labeled for OTC use only for the concurrent symptoms involved, i.e., "For the temporary relief of minor aches and pains with * * * heartburn, sour stomach, or acid indigestion * * *." See proposed § 343.60(b)(2) (53 FR 46258). Such products may be marketed pending issuance of a final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products and an amendment to the final monograph for OTC antacid drug products to provide for this new antacid-acetaminophen combination and dosage form. Marketers of such products are subject to the risk that the agency may, in the final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, or in the amendment to the final monograph for OTC antacid drug products, adopt a other regulatory action.

Because the antacid component of this combination drug product is regulated by a final monograph, marketing of antiacid-acetaminophen combination drug products with labeling that is not in accord with the labeling proposed in the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products (proposed 21 CFR part 343) and contained in the current final monograph for OTC antacid drug products (21 CFR part 331) may result in regulatory action against the product, the marketer, or both. The labeling for antacid-acetaminophen combination drug products in a solid oral dosage form is stated below. This labeling is required for marketing any antacid-acetaminophen combination drug product for ingestion in a solid oral dosage form.

Statement of Identity

For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For antacid-acetaminophen combination drug products, the statement of identity for the antacid component in § 331.30(a) and the statement of identity for the internal analgesic component in proposed § 343.50(a) must be used.

Indications

The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as identified in proposed § 343.60(b)(2).

Warnings

The labeling of the product states, under the heading "Warnings," the applicable warning(s) for each ingredient in the combination, as established in the warnings sections in § 331.30(c) and in proposed § 343.50(c) and in the drug interaction precautions section in § 331.30(d).

Directions

The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in section § 331.30(e) and in proposed § 343.50(d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in § 331.11 and in proposed § 343.50(d).

Warnings and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicate words or phrases so that the resulting information is clear and understandable.

The final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products and the amendment to the final monograph for OTC antacid drug products, when published, will establish the final labeling requirements for OTC antacid-acetaminophen combination drug products in a solid oral dosage form.

Interested persons may submit written comments to the Dockets Management Branch (address above). Such comments will be considered in determining whether further amendments to or revisions of this policy are warranted. Three copies of all comments shall be submitted, except that individuals may submit single copies. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 30, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-2727 Filed 2-4-92; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Low Income Levels for Health Professions and Nursing Programs

The Health Resources and Services Administration (HRSA) is updating income levels used to identify a "low income family" for the purpose of providing training for individuals from disadvantaged backgrounds under various health professions and nursing programs included in titles VII and VIII of the Public Health Service Act (the Act).

The Department periodically publishes in the **Federal Register** low income levels used by the Public Health Service for grants and cooperative agreements to institutions providing training for individuals from disadvantaged backgrounds. A "low income level" is one of the factors taken into consideration to determine if an individual qualifies as a disadvantaged student for purposes of health professions and nursing programs.

The programs under the Act that use "low income levels" as one of the factors in determining disadvantaged backgrounds include the Health Careers Opportunity Program (section 787), the Program of Financial Aid for Disadvantaged Health Professions Students (section 787(b)), the Scholarships for Undergraduate