parent of such individual (or the spouse of such a parent) who is living in the same household as such individual, whether or not such income is available to such individual. However, in the case of earned income (as defined in § 416.1102(b)) of the parent and spouse of such parent, such earned income will be reduced by $65 a month (or the amount of earned income if less than $65) for all expenses attributable to the earning of such income. In addition, such parent's and spouse of parent's income is reduced by $130 a month when there is one parent (or spouse of a parent) in the household or $195 a month when the parent and spouse of such parent both reside in the household and by an allocation of $65 a month for each ineligible child (as defined in § 416.1050) under age 21 of the parent or spouse of the parent residing in the household. However, any income of the ineligible child will be used to reduce his $65 allocation of income. The remaining income of the parent and spouse of such parent shall be deemed to be available to the eligible individual who is a child. Income deemed to the eligible child will be treated as unearned income.

(c) *Income not included.* For purposes of this section, the term income does not include: (i) assistance based on need and furnished by any State or political subdivision of a State (or the Bureau of Indian Affairs), or the payments made under title XVI of the Social Security Act and any income taken into account in determining the eligibility for and amount of such assistance or payments; (ii) any portion of any grant, scholarship, or fellowship used to pay the cost of tuitions and fees; (iii) amounts received for foster care of an ineligible child; (iv) bonus value of food stamps and the value of the Department of Agriculture donated foods; (v) home produce grown for personal consumption; (vi) refund of taxes paid on real property or food purchased by the family; and (vii) such income needed to fulfill an approved plan for achieving self-support. In determining the income of ineligible children in the household for purposes of allocating a share of the parent's income, the items enumerated shall be excluded and in addition, the total earned income of such child who is a student (subject to the limitation in § 416.1163) unless the child actually makes this income available to the family.

3. In § 416.1216, a new paragraph (c) is added to read as follows:

§ 416.1216 Exclusion of household goods and personal effects.

* * * * *

(c) *Additional exclusions of household goods and personal effects.* In determining the resources of an individual (and spouse, if any) and in determining the value of the household goods and personal effects of such individual (and spouse), there shall be excluded a wedding ring and an engagement ring and household goods and personal effects such as prosthetic devices, dialysis machines, hospital beds, wheel chairs and similar equipment required because of a person's physical condition. The exclusion of items required because of a person's physical condition is not applicable to items which are used extensively and primarily by members of the household in addition to the person whose physical condition requires the item.

[FR Doc.74-1778 Filed 1-21-74;8:45 am]

Food and Drug Administration

[21 CFR Part 130]

OVER-THE-COUNTER DRUGS GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

Revision of Tentative Final Order for Antacid Products; Modification of in Vitro Test

In the FEDERAL REGISTER of November 12, 1973 (38 FR 31260), the Commissioner of Food and Drugs published a tentative final monograph on over-the-counter (OTC) antacid drugs pursuant to 21 CFR 130.301(a)(7).

The proposed and tentative final monographs contained an in vitro test to measure the acid neutralizing capacity of an antacid product. The Commissioner stated in the preamble to the tentative final monograph that the Food and Drug Administration was conducting appropriate studies to validate the in vitro test. Pursuant to those tests, and taking into consideration the comments submitted on the proposal (see paragraphs 32 through 45 of the preamble to the tentative final order, published in the FEDERAL REGISTER on November 12, 1973 (38 FR 31263)), the Commissioner has determined that further modification of § 130.305(a)(1) is appropriate. Accordingly, the Commissioner is hereby publishing a revision of § 130.305(a)(1) as a new tentative final order.

Under § 130.305(a)(1)(i) of the tentative final order, temperature controlling equipment and a phototachometer or similar device were required. The revised test procedure requires a stirring speed (300 ± 30 r.p.m.). The person conducting the test may select any method to assure the speed is within the limits. The temperature does not have to be controlled as long as it is reasonable.

The variation found in disintegration time of antacid tablets made it impossible to obtain uniform acid neutralizing capacity values under the proposed test. It is therefore necessary to also establish a disintegration test for antacid tablets. The revised procedure requires that the tablet samples be of a uniform particle size. The disintegration test will determine how a product will be labeled. If the tablet disintegrates in 10 minutes or less, the manufacturer may recommend chewing or swallowing, at the patient's option. However, if the tablet does not dissolve in 10 minutes, the directions for use may only recommend chewing the tablet. The rationale for this requirement is that any tablet that takes longer than 10 minutes to disintegrate must be chewed to make the particle size appropriate to result in acid neutralization in the stomach in the first 10 minutes of use. The Tablet Disintegration Test Method described in The United States Pharmacopeia XVIII (page 932) shall be used with simulated gastric fluid test solution, listed on page 1026 of The United States Pharmacopeia XVIII, as the immersion fluid, with the time limit of 10 minutes. Any tablets not meeting this standard must recommend chewing in its directions for use. A time limit for disintegration on the chewed tablets is not necessary because the tablet must pass the preliminary antacid test.

The preliminary antacid test is an adaptation of that proposed by the Advisory Review Panel, except that all tablet samples will be in a uniform particle form and wetted with ethanol to prevent any floating particles. In addition, a procedure for chewing gum containing the antacid in the coating has been included.

The major change from the test proposed by the Panel is in the acid neutralizing capacity part of the test. Under the proposed test, the rate of adding the acid to the sample affected the neutralizing capacity value obtained and may have favored the fast-acting strong alkaline ingredients. Since the rate of adding the acid affected the final values, it was impossible to validate that part of the proposed test procedure. Once a product qualifies as an antacid, the critical factor is the product's potential for neutralizing acid, i.e. neutralizing capacity. Therefore, the most appropriate procedure is to add sufficient acid to neutralize all the antacid and back titrate with a basic solution. This change in the test eliminates the rate of addition of acid as a variable and also the problems caused by faster-acting and buffered antacid ingredients.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 321, 352, 355, 371), the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended; 5 U.S.C. 553, 554, 702, 703, 704), and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs is proposing to revise § 130.305(a)(1) of the tentative final monograph, published in the FEDERAL REGISTER of November 12, 1973 (38 FR 31260), to read as follows:

§ 130.305 Antacids.

* * * * *

(a) * * *

(1) The neutralizing capacity of the products shall be measured in the following way:

(i) *Apparatus and reagents.* (*a*) pH meter, equipped with glass and saturated calomel electrodes.

(*b*) Magnetic stirrer.

(*c*) Magnetic stirring bars (about 40 mm. long and 10 mm. in diameter).

(*d*) 50 ml. buret.

(*e*) Buret stand.

(*f*) 100 ml. beakers (45 mm. inside diameter).

(*g*) 250 ml. beakers.

(*h*) 10 ml., 20 ml. and 30 ml. pipets calibrated to deliver.

(*i*) Tablet comminuting device.

(*j*) Number 20 standard mesh sieve.

(*k*) Tablet disintegration apparatus.

(*l*) 0.1 N, 0.5 N and 1.0 N hydrochloric acid.

(*m*) 0.5 N sodium hydroxide.

(*n*) Standard pH 4.0 buffer solution (0.05 M potassium hydrogen phthalate).

(*o*) 95 percent ethanol.

(ii) *Procedure*—(*a*) *Reagent standardization.* Standardize the sodium hydroxide (NaOH) and hydrochloric acid (HCl) solutions according to the procedures in The United States Pharmacopeia XVIII (NaOH page 1036 and HCl page 1034) or the Official Methods of Analysis of the Association of Official Analytical Chemists, 11th Ed., 1970, (NaOH page 876 and HCl page 873).[1]

(*b*) *Disintegration test.* A tablet disintegration test shall be performed on tablets that are not to be chewed following the procedures described in the United States Pharmacopeia XVIII (page 932). If the label states the tablet may be swallowed, it must disintegrate within a 10 minute time limit pursuant to the test procedure using simulated gastric fluid test solution, The United States Pharmacopeia XVIII page 1026, rather than water as the immersion fluid.

(*c*) *Preliminary antacid test*—(*1*) *pH meter.* Standardize the pH meter at pH 4.0 with the standardizing buffer and at pH 1.1 with 0.1 NHC1.

(*2*) *Liquid sample.* Place an accurately weighed and well mixed amount of the antacid product equivalent to the minimum labeled dosage, e.g. 5 ml., into a 100 ml. beaker. Add sufficient water to obtain a total volume of about 40 ml. and mix on magnetic stirrer at 300 ± 30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in subdivision (ii) (*c*) (*6*) of this subparagraph.

(*3*) *Chewable and non-chewable tablet sample.* Place an accurately weighed amount of a tablet composite equivalent to the minimum labeled dosage into a 100 ml. beaker. (The composite shall be prepared by determining the average weight of not less than 20 tablets and then comminuting the tablets sufficiently to pass through a number 20 standard mesh sieve. Mix the sieved material to obtain a uniform sample.) Add 5 ml. of 95 percent ethanol, mix to thoroughly wet the sample and add water to a volume of 40 ml. and mix on magnetic stirrer at 300±30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in subdivision (ii) (*c*) (*6*) of this subparagraph.

(*4*) *Effervescent sample.* Place an amount equivalent to the minimum labeled dosage into a 100 ml. beaker. Add 10 ml. water and swirl the beaker gently while allowing the reaction to subside. Add another 10 ml. of water and swirl the beaker gently. Wash down the walls of the beaker with 20 ml. of water and mix on magnetic stirrer at 300±30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in subdivision (ii) (*c*) (*6*) of this subparagraph.

(*5*) *Chewing gum samples with antacid in coating.* Place the number of pieces of gum equivalent to the minimum labeled dosage in a 100 ml. beaker. Add 40 ml. of water and mix on magnetic stirrer at 300±30 r.p.m. for about 2 to 3 minutes. Analyze the sample according to the procedure set forth in subdivision (ii) (*c*) (*6*) of this subparagraph.

(*6*) *Test procedure.* (*i*) Add 10.0 ml. 0.5 HCl to the test solution while stirring on the magnetic stirrer at 300±30 r.p.m.

(*ii*) Stir for exactly 10 minutes.

(*iii*) Read and record pH.

(*iv*) If pH is below 3.5, the product shall not be labeled as an antacid. If the pH is 3.5 or greater, determine the acid neutralizing capacity according to the procedure set forth in subdivision (ii) (*d*) (*6*) of this subparagraph.

(*d*) *Acid neutralizing capacity test*—(*1*) *pH meter.* Standardize the pH meter at pH 4.0 with the standardizing buffer and at pH 1.1 with 0.1 N HC1.

(*2*) *Liquid sample.* Place an accurately weighed and well mixed amount of product equivalent to the minimum labeled dosage (e.g. 5 ml., etc.) into a 250 ml. beaker. Add sufficient water to obtain a total volume of about 70 ml. and mix on the magnetic stirrer at 300 ± 30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in subdivision (ii) (*d*) (*6*) of this subparagraph.

(*3*) *Chewable and non-chewable tablet sample.* Place an accurately weighed amount of a tablet composite equivalent to the minimum labeled dosage into a 250 ml. beaker. (The composite shall be prepared by determining the average weight of not less than 20 tablets and then comminuting the tablets sufficiently to pass through a number 20 standard mesh sieve. Mix the sieved material to obtain a uniform sample). Add 5 ml. of 95 percent ethanol, mix to thoroughly wet the sample and add water to a volume of 70 ml. and mix on magnetic stirrer at 300 ± 30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in subdivision (ii) (*d*) (*6*) of this subparagraph.

(*4*) *Effervescent sample.* Place an amount equivalent to the minimum labeled dosage into a 250 ml. beaker. Add 10 ml. water and swirl the beaker gently while allowing the reaction to subside. Add another 10 ml. of water and swirl the beaker gently. Wash down the walls of the beaker with 50 ml. of water and mix on magnetic stirrer at 300±30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in subdivision (ii) (*d*) (*6*) of this subparagraph.

(*5*) Chewing gum sample and test procedure *with antacid in coating.* Assay six pieces of gum individually in the following manner.

(*i*) Place one piece of gum in a 250 ml. beaker and add 50 ml. of water.

(*ii*) Pipette in 30.0 ml. of 1.0 N HCl and stir on magnetic stirrer at 300±30 r.p.m.

(*iii*) Stir for exactly 10 minutes.

(*iv*) Stop the stirrer and remove the gum using a long needle or similar utensil.

(*v*) Rinse the long needle or utensil and the gum with 20 ml. of water into the sample beaker.

(*vi*) Stir for exactly 5 minutes.

(*vii*) In a period of time not to exceed 5 minutes titrate the excess 1.0 N HCl with 0.5 N NaOH to pH 3.5.

(*vii*) Check sample solution 10 to 15 seconds after obtaining pH 3.5 to make sure the pH is stable.

(*ix*) Average the results of the six individual assays and calculate the total mEq. based on the minimum labeled dosage as follows:

mEq./piece of gum = (30.0 ml.) (N of HCl) − (ml. of NaOH) (N of NaOH).

Total mEq. = (number of pieces of gum in minimum dosage) × (mEq./piece of gum).

(*6*) *Acid neutralizing capacity test procedure (except chewing gum).* (*i*) *Pipette* 30.0 ml. of 1.0 N HCl into the sample solution while stirring on the magnetic stirrer at 300±30 r.p.m.

(*ii*) Stir for exactly 15 minutes.

(*iii*) In a period not to exceed an additional 5 minutes titrate the excess 1.0 N HCl with 0.5 N NaOH to pH 3.5.

(*iv*) Check the sample solution 10 to 15 seconds after obtaining pH 3.5 to make sure the pH is stable.

(*v*) Calculate the number of mEq. of acid neutralized by the sample as follows:

Total mEq. = (30.0 ml.) (N of HCl) − (ml. of NaOH) (N of NaOH).

Use appropriate factors, i.e. specific gravity, average tablet weight etc. to calculate the total mEq. of acid neutralized per minimum labeled dosage.

(iii) *Test modifications.* The formulation and/or mode of administration of certain products may require modification of this in vitro test. Any proposed modification shall be submitted to the Food and Drug Administration for approval.

* * * * *

Interested persons may file written objections and request an oral hearing before the Commissioner regarding this tentative final order on or before February 21, 1974. To be considered such objections or request shall be received by the Hearing Clerk (rather than simply mailed) by the close of business on or before February 21, 1974. Request for an oral hearing shall specify points to be covered and time requested.

All objections and requests shall be addressed to the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, and may be accompanied by a memorandum or brief in support thereof. Received objections and requests may be seen in the above office during working hours, Mon-

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044.

day through Friday. Any scheduled oral hearing will be announced in the FEDERAL REGISTER.

Dated: January 16, 1974.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.74-1821 Filed 1-21-74;8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[49 CFR Part 232]

[FRA Petition No. 93]

NOTICE OF TRAIN AIR BRAKE TEST PROGRAM

Maximum Allowable Brake Pipe Leakage

Notice is hereby given that on January 10, 1974, the FRA Railroad Safety Board approved a test program as set forth below to determine the feasibility of increasing the maximum allowable brake pipe leakage prescribed in §§ 232.12(b)(1) and 232.13(d)(1) from 5 pounds to 8 pounds during below freezing weather on freight trains hauled by locomotives with pressure maintaining type automatic brake valves controlling train air brake operation when the brake pipe pressure gradient (difference between pressures at the head and rear end) does not exceed 15 pounds.

Experience indicates that during cold weather numerous minute brake pipe leaks occcur due to hardening of rubber and gasket materials and shrinkage of metal parts. These leaks are often extremely difficult if not impossible to detect and correct. In these circumstances, attempts to comply with the 5 pound brake pipe leakage limit often results in needless prolonged delays of trains or substantial reductions in the lengths of trains.

Modern locomotive air brake equipment has a pressure maintaining feature which compensates for leakage of more than 10 pounds per minute. This feature holds service brake pipe reduction constant at the value selected by the engineman. In the absence of this feature, brake pipe leakage increases the reduction value selected by the engineman and could increase it to the extent that "overbraking" of the train occurs. Thus, the pressure maintaining feature gives the engineman better control of the train brakes.

APPROVED TEST PROGRAM

Participating Carriers

Southern Railway Company;
The Cincinnati, New Orleans, and Texas Pacific Railway Company;
The Alabama Great Southern Railroad Company;
Union Pacific Railroad Company;
Penn Central Transportation Company;
Chicago and North Western Transportation Company; and
Chicago, Milwaukee, St. Paul and Pacific Railroad.

Test period. January 15–April 15, 1974.

Trains. This test is limited to freight trains other than "run-through" and "unit run-through" trains operated in accordance with 49 C.F.R. 232.10 and interchanged with non-participating carriers, which are hauled by locomotives with pressure maintaining type automatic brake valves controlling train air brake operation.

Mandatory Brake Test Procedures. (1) The air brake system on a freight train prior to making train air brake system tests must be charged to within 15 pounds of the setting of the brake pipe pressure regulating valve on the locomotive, but in no case to less than 60 pounds, as indicated by an accurate gage at rear end of train;

(2) Pressure maintaining feature must be cut out and not functioning during brake pipe leakage tests;

(3) Leakage in excess of 5 pounds per minute, and not exceeding 8 pounds per minute, is permissible if, in the opinion of qualified personnel, the excess leakage is caused by below freezing weather, does not result from equipment defects, and does not constitute a hazard.

Reporting of Test Results. For each 30 day period, a written report summarizing each freight train operation with brake pipe leakage of 5 to 8 pounds per minute must be prepared and sent to Associate Administrator for Safety, RA-60, Federal Railroad Administration, 2100 Second Street, S.W., Washington, D.C. 20590. Each report must be received within 15 days following the end of the 30 day period and must contain the following:

1. Date and time,
2. Location, also state whether initial terminal or other;
3. Temperature and weather;
4. Type of train (general merchandise, high priority freight, unit, etc.);
5. A description of train consist including number of locomotive units and cars and tonnage;
6. Brake pipe leakage;
7. Statement of delay, if any, caused by working train in attempt to minimize leakage, including description of work done;
8. Narrative description of any significant circumstances other than those tabulated above, including any unusual delays or occurrences enroute which might be connected with train handling, and an estimate of penalty, such as additional delay or extent of train consist reduction, which would have resulted if the leakage has been reduced to 5 pounds per minute.

This notice is issued under the authority of section 202, 84 Stat. 971, 45 U.S.C. 431; and § 1.49(n) of the regulations of the Office of the Secretary of Transportation, 49 C.F.R. 1.49(n).

Issued in Washington, D.C. on January 17, 1974.

DONALD W. BENNETT,
Chief Counsel.

[FR Doc.74-1789 Filed 1-21-74;8:45 am]

National Highway Traffic Safety Administration

[49 CFR Part 571]

[Docket No. 73-34; Notice 1]

SCHOOL BUS BODY JOINT STRENGTH

Notice of Proposed Rulemaking

NOTE: This notice is a republication of a similarly-titled notice of proposed rulemaking published January 7, 1974. Due to a clerical error, the notice published reproduced an earlier draft of the signed original. Interested parties should substitute the notice set forth below for the one published January 7, 1974.

This notice proposes a motor vehicle safety standard that will require the sheet metal panels and other structural parts of school bus bodies to be more strongly joined, thereby providing greater safety for school children in crashes.

In several bus accident investigations since 1967, the National Transportation Safety Board (NTSB) has pointed to the failure of sparsely riveted bodies as a factor contributing to deaths and injuries in school bus accidents. The NTSB studies suggest that failure of the bus joints contributes to disintergration of the bus body and occupant ejection, and that the edges of the opened joints cause lacerative injuries.

Upon reviewing the available accident information, the recommendations of the NTSB and the current construction practices in the school bus industry, this agency has tentatively concluded that practicable methods exist to increase the strength of school bus bodies and that the adoption of these methods will save lives and mitigate injuries. The standard hereby proposed will require each joint to have at least 60% of the strength of the weakest joined part. The requirement derives from section 5.6 of the Vehicle Equipment Safety Commission's Regulation VESC-6, *Minimum requirements for school bus design and equipment,* whose adoption has been urged both by the NTSB and by several consumer interest groups, headed by B.U.S. W.R.E.C., who have jointly filed a petition for rulemaking on this subject.

The basic intent of the 60 percent strength requirement is that each joint must be capable of providing a relatively high proportion of the strength of the joined materials. For example, if the sheet metal panels forming the sides of the bus are capable of sustaining a tensile force of 40,000 pounds per square inch of cross sectional area, the joints that connect the panels must be capable of sustaining a force of 24,000 pounds per square inch of cross sectional area. This relative level of strength is well within the capacity of conventional joining methods, and the means of strengthening a deficient joint to reach this level are usually straight-forward: if a riveted joint is took weak, the manufacturer may simply install more rivets, at closer intervals.

In order to bring the basic VESC-6 requirement into a form that satisfies the legal and operational requirements of the motor vehicle safety standards, the agency has included a test procedure to make possible an objective determination of a joint's strength. Under this procedure, a testing agency would cut a joint or joint segment at random from the bus together with specified portions of the joined parts, and subject the resulting test specimen to a tensile test in a tension testing machine. If the specimen withstands the required force before it breaks, that particular portion of the joint satisfies the requirement.

Although the procedure could theoretically produce an indeterminate number of tests, in practice a manufacturer