(i) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(ii) *Lot size.* The number of primary containers or units in the lot.

(iii) *Sample size (n).* The total number of sample units drawn for examination from a lot.

(iv) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for examination or testing as a single unit.

(2) Sampling plans:

Lot size (primary containers):	Size of container [1] (n)
4,800 or less	13
4,801 to 24,000	21
24,001 to 48,000	29
48,001 to 84,000	48
84,001 to 144,000	84
144,001 to 240,000	126
Over 240,000	200

[1] Net weight equal to or less than 1 kg. (2.2 lb).

Lot size (primary containers):	Size of container [1] (n)
2,400 or less	13
2,401 to 15,000	21
15,001 to 24,000	29
24,001 to 42,000	48
42,001 to 72,000	84
72,001 to 120,000	126
Over 120,000	200

[1] Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kgs (10 lb).

(c) If canned salmon falls below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.7(b) of this chapter, in the manner and form therein specified.

Any person who will be adversely affected by the foregoing order may at any time on or before June 23, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective on July 22, 1975, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1046, 1055–1056, as amended, 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371))

Dated: May 15, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75–13546 Filed 5–22–75;8:45 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 331—ANTACID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Revised Effective Dates

The Commissioner of Food and Drugs is extending the effective date to September 2, 1975 for labeling of antacid and antiflatulent products not receiving an extension of the effective date for reformulation.

In the FEDERAL REGISTER of June 4, 1974 (39 FR 19862), the Commissioner promulgated a final order for antacid and antiflatulent Over-the-Counter (OTC) products generally recognized as safe and effective and not misbranded. Paragraph 82 of the preamble of that order states that the Commissioner concluded that it was reasonable to establish the following conditions for the effective date of the final monograph: "The effective date of the monograph will be July 5, 1974, with the following exceptions. The effective date for all labeling for products not receiving an extension of the effective date for reformulation shall be June 5, 1975. Where reformulation is necessary, and if sufficient data and reasons are supplied, the Commissioner will grant an extension of the effective date for reformulation and relabeling for up to 2 years after the date of publication in the FEDERAL REGISTER."

The Commissioner has received requests and petitions from major manufacturers of OTC antacid products and from a trade association requesting that the effective date for all labeling for products not receiving an extension for reformulation be extended beyond June 5, 1975.

One trade association has petitioned to allow an orderly inclusion of the general warning statement required by § 330.1(g) (21 CFR 330.1(g)) of the regulations and has commented on the recent change in that warning published in the FEDERAL REGISTER of March 13, 1975 (40 FR 11717). It was noted that in order to comply with the June 5, 1975 effective date for the antacid and antiflatulent monographs, many OTC antacid and antiflatulent manufacturers have ordered, received, and in some instances, affixed to the container the labeling for their antacid and antiflatulent products, but because of the changes in the general warning published recently, these same manufacturers do not have either the exact language on their current stocks of labeling, or due to the uncertainty of the adoption and specific language of the regulation prior to publication, do not have any similar language on their labeling. Therefore, it was petitioned that manufacturers and distributors who have already ordered and received such labeling be allowed to use labeling stock that otherwise complied with the monographs and to include the general warning required by § 330.1(g) in their next labeling order.

There was comment from manufacturers that, due to severe shortages besetting the paper industry and uncertainties arising from the energy crisis, stocks and labeling had to be ordered in greater quantities and that an unanticipated sharp downswing in the economy has aggravated the over-supply situation of such stocks and labeling. It was noted that destruction of this substantial amount of stock would create a severe financial hardship for the companies and would not be in the public interest. Therefore, it was petitioned that the effective date of the final order be stayed for a period of 4 to 6 months.

The Commissioner concludes that there are valid reasons to allow an extension beyond June 4, 1975 of the effective date of the OTC antacid and antiflatulent monographs. First the Commissioner concludes that the March 13, 1975 publication in the FEDERAL REGISTER of the final order for the general warning (40 FR 11717) did not provide sufficient time for including the general warning statement required by § 330.1(g) and that labeling which otherwise complies with the monograph should be used until new labeling is ordered.

The Commissioner is also aware that in some instances a downward trend in the economic picture may have resulted in an overstock situation. The Commissioner agrees that for the companies this condition would create an economic waste, the cost of which would ultimately be passed on to the consumer which would not be in the public interest.

However, taking into consideration all of the reasons given for an extension of time of the effective date of the OTC antacid and antiflatulent monographs, the Commissioner concludes that it is not in the best interest of the consumer to allow an indefinite period of time to elapse before requiring all manufacturers and distributors to be in compliance with the monographs. Accordingly, he has determined that a 90-day extension for compliance shall be provided for those products for which there is no extension of the effective date for reformulation. The revised effective date for all labeling for these products shall be September 2, 1975.

Recognizing that there has been only a short period of time since the general warning final order of March 13, 1975 was published, the Commissioner additionally concludes that, if there is compliance with the labeling requirements of the antacid and antiflatulent monographs in all other respects at the end of the 90-day extension period, manufacturers and distributors should be permitted to use labeling stock and include

the general warning revision in their next labeling order.

The Commissioner concludes that the extension does not affect the effective date, where an extension has been granted for reformulation and relabeling.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetics 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)), (5 U.S.C. 553, 554, 702, 703, 704) and under authority delegated to the Commissioner (21 CFR 2.120), the effective dates for 21 CFR Parts 331 and 332 are revised as follows:

Effective date. All labeling for products not receiving an extension of the effective date for reformulation shall become effective on September 2, 1975, and where reformulation is necessary and an extension is granted the labeling requirements shall become effective on June 4, 1976.

Since the amendment established by this order grants relief of a restriction, namely the June 4, 1975 effective date previously published, notice and public procedure and delayed effective date are not prerequisites to this promulgation.

Effective date: This order shall be effective on May 23, 1975.

(Secs. 201, 502, 505, 701, Pub. L. 717, 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); (5 U.S.C. 553, 554, 702, 703, 704))

Dated: May 19, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75–13578 Filed 5–22–75;8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

Change in Sponsor

Correction

In FR Doc. 75–11385 appearing on page 18993 in the issue for Thursday, May 1, 1975, in § 510.600(c)(2) the second and third lines of Drug listing No. 000381 should be reversed.

SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

PART 1240—CONTROL OF COMMUNICABLE DISEASES

Ban on Sale and Distribution of Small Turtles

An order published in the FEDERAL REGISTER of November 18, 1972 (37 FR 24670) amended Parts 71 and 72 of Title 42, Code of Federal Regulations, by establishing §§ 71.171 through 71.176 (42 CFR 71.171 through 71.176) which provide for a general prohibition on the importation of certain small pet turtles and viable turtle eggs, and § 72.26 (42 CFR 72.26) (now § 1240.62 (21 CFR 1240.62) pursuant to transfer and recodification of the sections of 42 CFR Part 72 appropriate to Food and Drug function, published in the FEDERAL REGISTER of February 6, 1975 (40 FR 5620)) which required that pet turtles shipped in interstate commerce be tested for and certified free of *Salmonella* and *Arizona* organisms by the appropriate public health officials in the State of origin. The order was based upon epidemiological investigations that have shown that small pet turtles are a particularly significant source and reservoir of bacteria of the genera *Salmonella* and *Arizona*, both of which can cause, among other things, acute gastrointestinal illness in humans. Data and other information on the hazards of such bacteria and on the extent of turtle-associated disease are on display in the office of the Hearing Clerk.

There is continuing evidence, however, that the certification requirements have had limited effectiveness in preventing contaminated turtles from reaching pet owners. Although the certification program appears to have curtailed the number of turtles being shipped in interstate commerce, a recent survey of turtles certified between December 1972 and December 1973 completed by the Public Health Service Center for Disease Control shows that 54 percent of the turtles were contaminated by *Salmonella* and *Arizona* when retested some time subsequent to certification. The State of New Jersey has sampled six lots of turtles shipped to that State and detected *Salmonella* in five of the lots. Furthermore, the Food and Drug Administration has taken five selective samples of turtles certified by State health authorities and found *Salmonella* and *Arizona* organisms in three of the five samples. Four out of the five selected water samples in which turtles have been held were positive for *Salmonella*. Moreover, the Center for Disease Control has reported cases of salmonellosis in California, Oregon, and Tennessee associated with turtles from certified lots.

As recently as August 19, 1974, a batch of approximately 16,000 turtles was certified by the Louisiana State Department of Health as *Salmonella*- and *Arizona*-free. A sample collected from this same lot of 16,000 turtles on inspection August 21 and 22, 1974, in Pierre Part, Louisiana, was later found by the Dallas Laboratory of the Food and Drug Administration to be positive for *Arizona*. Three official samples were collected and analyzed from interstate shipments of this lot of turtles. All samples were subsequently found to be positive for *Arizona*. On October 18, 1974, the Food and Drug Administration undertook to issue Letters of Demand for Destruction by its district offices to all dealers handling turtles from this lot.

Prior to this most recent action against certified but contaminated turtles, the Commissioner of Food and Drugs, realizing that the present certification program was not preventing contaminated turtles from reaching the market, issued two proposals published in the FEDERAL REGISTER of May 28, 1974 (39 FR 18463) for consideration as possible solutions to the contaminated turtle problem: first, a complete ban on the sale and distribution of small turtles and, second, improvement of the certification scheme with imposition of additional requirements on the sale and shipment of turtles.

The preamble to those proposals pointed out that studies of salmonellosis have resulted in estimates that 14 percent of all human cases of salmonellosis are turtle-associated. It is thus possible that as many as 280,000 of the estimated 2,000,000 cases of salmonellosis in the United States each year are turtle-related.

Children are particularly susceptible to salmonellosis, tend to have more severe cases than adults, and are subject to infection transmitted when playing with pet turtles.

Finally, it was pointed out by the Animal Welfare Institute that small turtles sold in pet shops are not miniature, but baby turtles, mostly red-eared sliders, which under proper care can attain a shell length ranging from 6 to 11 inches and can live more than 40 years in captivity; yet 90 percent of the pets survive only 4 to 6 months.

Two hundred and forty-eight comments were received in response to the proposals from individual citizens, members of Congress, Federal, State and local officials, consumer groups, educational institutions, industry and professional groups, and turtle fanciers and their associations. Thirty-four comments opposed both proposals. Thirty-seven comments endorsed the improvement of the certification scheme and the imposition of additional requirements on the sale and shipment of turtles and turtle eggs. An additional comment opposing the ban addressed the statistical relationship between turtle ownership and its impact on human salmonellosis. One hundred and twenty-eight comments endorsed the proposal banning sale of small turtles. An additional comment endorsing the ban suggested that the ban include all turtles regardless of size or species and that a permit from the Commissioner be required by the purchaser before an exemption will be granted for bona fide scientific, educational, or exhibitional purposes. Two comments did not believe that the improvement of the certification scheme and the imposition of additional requirements on the sale and shipment of small turtles would be effective in dealing with the existing public health hazard. Ten comments requested that the sale of pet turtles be prohibited until the turtle industry demonstrates its ability to produce *Salmonella*- and *Arizona*-free turtles. Two comments requested a moratorium of 1 year on the banning of turtles from the market so that a study could be made to determine whether *Salmonella*- and *Arizona*-free turtles can be produced. Twenty-two