Proposed Rule Making

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 1050]

MILK IN THE CENTRAL ILLINOIS MARKETING AREA

Notice of Proposed Suspension of Certain Provisions of the Order

Notice is hereby given that, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), the suspension of certain provisions of the order regulating the handling of milk in the central Illinois marketing area is being considered for the month of August 1972.

All persons who desire to submit written data, views, or arguments in connection with the proposed suspension should file the same with the Hearing Clerk, Room 112–A, Administration Building, U.S. Department of Agriculture, Washington, D.C. 20250, not later than 3 days from the date of publication of this notice in the FEDERAL REGISTER. All documents filed should be in quadruplicate.

All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business horus (7 CFR 1.27(b)).

The provisions proposed to be suspended are as follows:

1. In § 1050.14, paragraphs (c) (2) and (3).

Statement of consideration. The proposed suspension action would permit unlimited diversion of producer milk under the central Illinois order for the month of August 1972 under the same rule of unlimited diversions as applied in May, June, and July 1972.

The suspension action was requested by Associated Milk Producers, Inc. The producer association claims that such action is necessary in order to enable its member producers to maintain producer status under the order for the month of August. A distributing plant to which a number of the association's member producers ship has been experiencing a decline in Class I sales along with an increase in Class II sales. Specialization in Class II products at this particular plant, lack of Class I sales to schools during August, and increasing competition from other handlers were cited as reasons for the current situation. Suspension of the diversion limitations was requested to facilitate the orderly disposition of reserve milk and to provide continued producer status for the aforementioned producers under the order.

Signed at Washington, D.C., on August 9, 1972.

JOHN C. BLUM,
Deputy Administrator,
Regulatory Programs.

[FR Doc.72-12843 Filed 8-14-72;8:48 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 130]

LEGAL STATUS OF APPROVED LABELING FOR PRESCRIPTION DRUGS; PRESCRIBING FOR USES UNAPPROVED BY THE FOOD AND DRUG ADMINISTRATION

Notice of Proposed Rule Making

The widespread use of certain prescription drugs for conditions not named in the official labeling has led to questions concerning the legal responsibilities of the prescribing physicians, and the position of the Food and Drug Administration with respect to such use. Accordingly, the Commissioner proposes to add a new regulation clarifying the applicable legal requirements and specifying actions that may be taken by the Food and Drug Administration with respect to unapproved uses of approved prescription drugs.

Section 505 of the Federal Foqd, Drug, and Cosmetic Act prohibits the introduction or delivery for introduction into interstate commerce of any new drug without the filing of an investigational new drug plan or approval of a new drug application. Unlike the adulteration and misbranding provisions of the Act, the new drug provisions apply only at the moment of shipment in interstate commerce and not to action taken subsequent to shipment in interstate commerce. In United States v. Phelps Dodge Mercantile Co., 157 F. 2d 453 (9th Cir. 1946), cert. denied, 330 U.S. 818 (1947), the court held that violations while products are held for sale after interstate shipment did not come within the jurisdiction of the Act. As a result of that decision, Congress enacted the Miller amendment of 1948, 62 Stat. 582, amending section 301(k) of the Act to extend the reach of the adulteration and misbranding provisions of the Act to violations after interstate shipment. The 1948 amendment did not, however, also extend the reach of the new drug provisions of the Act, which are separate from the adulteration and misbranding provisions, to action taken after interstate shipment.

The major objective of the drug provisions of the Federal Food, Drug, and Cosmetic Act is to assure that drugs will be safe and effective for use under the conditions of use prescribed, recommended, or suggested in the labeling thereof. Thus, new drug approval and antibiotic drug certification are regulated by law, both in the prescriber's and the patient's interest. When a new drug is approved for marketing, the conditions of use that have been approved are required to be set forth in detail in the official labeling. This labeling must accompany the drug in interstate shipment and must contain adequate information for safe and effective use of the drug, including: Indications, effects, dosages, routes, methods, and frequency and duration of administration, contraindications, side effects, and precautions. The labeling is derived from the data submitted with the new drug application. It presents a full disclosure summarization of drug use information, which the supplier of the drug is required to develop from accumulated clinical experience, and systematic drug trials consisting of preclinical investigations and adequate well-controlled clinical investigations that demonstrate the drug's safety and the effectiveness it purports or is represented to possess.

If an approved new drug is shipped in interstate commerce with the approved package insert, and neither the shipper nor the recipient intends that it be used for an unapproved purpose, the requirements of section 505 of the Act are satisfied. Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.

This interpretation of the Act is consistent with congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to enactment, there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient. Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.

In the 1938 Act and the 1962 amendments, however, Congress clearly required the Food and Drug Administration to control the availability of drugs for prescribing by physicians. Under the 1938 Act, a new drug could not be marketed unless a new drug application establishing the drug's safety had been allowed to become effective by the Food and Drug Administration. Under the 1962 amendments, no new drug is permitted on the market until the Food and Drug Administration approves a new drug application demonstrating both its safety and effectiveness.

Under the 1962 amendments, moreover, the Food and Drug Administration is required to review the labeling for every new drug, including the package insert for prescription new drugs, and to approve it as not false or misleading in any particular. In approving the labeling the Food and Drug Administration must determine both that the content is entirely truthful, and that it omits no information pertinent to the safe and effective prescribing of the drug by the physician. Congress intended the labeling to be a full, complete, honest, and accurate appraisal of the important facts that have reliably been proved about the drug.

Thus, although it is clear that Congress did not intend the Food and Drug Administration to regulate or interfere with the practice of medicine, it is equally clear that it did intend that the Food and Drug Administration determine those drugs for which there exists substantial evidence of safety and effectiveness and thus will be available for prescribing by the medical profession, and additionally, what information about the drugs constitutes truthful, accurate, and full disclosure to permit safe and effective prescription by the physician. As the law now stands, therefore, the Food and Drug Administration is charged with the responsibility for judging the safety and effectiveness of drugs and the truthfulness of their labeling. The physician is then responsible for making the final judgment as to which, if any, of the available drugs his patient will receive in the light of the information contained in their labeling and other adequate scientific data available to him.

Although the Act does not require a physician to file an investigational new drug plan before prescribing an approved drug for unapproved uses, or to submit to the Food and Drug Administration data concerning the therapeutic results and the adverse reactions obtained, it is sometimes in the best interests of the physician and the public that this be done. The physician should recognize that such use is investigational, and he should take account of the scientific principles, including the moral and ethical considerations, applicable to the safe use of investigational drugs in human patients. When the results of treatment are reported completely and accurately the data may be helpful to patients and physicians as well as to the Food and Drug Administration. Such information can lead to warnings against dangerous unapproved uses, or, on the other hand, to acceptance of previously unknown uses.

Physicians have been concerned that the failure to follow the labeling of a drug may render them unduly liable for malpractice.

Although labeling, along with medical articles, tests, and expert opinion, may constitute evidence of the proper practice of medicine, it is not controlling on this issue. The labeling is not intended either to preclude the physician from using his best judgment in the interest of the patient, or to impose liability if he does not follow the package insert. A physician should recognize, however, that the package insert represents a summary of the important information on the conditions under which the drug has been shown to be safe and effective by adequate scientific data submitted to the Food and Drug Administration.

Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. Several alternative courses of action are available to the Food and Drug Administration under these circumstances, depending upon the specific facts of each case. These actions include: Requiring a change in the labeling to warn against or to approve the unapproved use, seeking substantial evidence to substantiate the use, restricting the channel of distribution, and even withdrawing approval of the drug and removing it from the market in extreme cases. When necessary, the Food and Drug Administration will not hesitate to take whatever action of this nature may be required to bring possible harmful use of an approved drug under control.

Section 1.106 of the regulations (21 CFR 1.106) requires the labeling to contain appropriate information with respect to all intended uses of the drugs. Thus, where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or to the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly.

The Commissioner believes it important that the public, the medical profession, and the pharmaceutical industry fully appreciate the statutory provisions enacted by Congress that are controlling under these circumstances.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 701, 76 Stat. 781–785, as amended, 52 Stat. 1055–1056; 21 U.S.C. 355, 371) and under authority delegated to the Commisioner (21 CFR 2.120), it is proposed that the following new section be added to Part 130:

§ 130.____ Legal status of labeling, including package inserts and product brochures, for prescription drugs; prescribing for uses unapproved by the Food and Drug Administration.

(a) The Food and Drug Administration approves labeling for a prescription new drug as part of the new drug approval process. Supplemental new drug applications may periodically result in revision of the labeling.

(1) The labeling approved by the Food and Drug Administration in a prescription new drug application summarizes all information with respect to the conditions of use for which substantial evidence is available to the Food and Drug Administration that the drug is safe and effective.

(2) A prescription new drug may not be shipped in interstate commerce when intended for uses not contained in the currently approved labeling. Such unapproved uses may include, inter alia, a different dosage, or a different patient population, or a different regimen, than that approved. Section 505 of the Federal Food, Drug, and Cosmetic Act requires that a manufacturer, physician, or other person who ships or requests shipment of a prescription new drug in interstate commerce with the intent, or for the purpose, of an unapproved use must first file with the Food and Drug Administration an investigational new drug plan as set out in § 130.3.

(3) Once a prescription new drug has been shipped in interstate commerce intended for its approved use(s) under approved labeling, the Federal Food, Drug, and Cosmetic Act does not require a physician to file with the Food and Drug Administration an investigational new drug plan in order to lawfully prescribe the drug for an unapproved use, when such prescribing is done as part of the practice of medicine.

(b) When an unapproved use of a new drug may endanger patients or create a public health hazard, or provide a benefit to patients or to the public health, the Food and Drug Administration is obligated to take one or more of the following courses of action:

(1) Revision of the package insert may be required to add a specific contraindication or warning against the unapproved use.

(2) The manufacturer may be required to obtain and submit the available data with respect to the unapproved use, or to sponsor clinical trials to determine the safety and effectiveness of the drug for the unapproved use.

(3) If substantial evidence of safety and effectiveness is available, revision of the package insert may be permitted or required to add the unapproved use as an approved use and to state the conditions under which the drug is safe and effective for that use.

(4) Revision of the package insert may be required to state that a prescription for the drug should not be refilled.

(5) Revision of the package insert may be required to state that the drug should be distributed only through specified channels (e.g., hospital pharmacies) and/or should be prescribed dispensed, or administered only by physicians with specified qualifications.

(6) The investigational new drug authority, as well as the new drug approval authority, may be invoked to impose a

requirement that the drug may be distributed only through specified channels and/or may be prescribed, dispensed, or administered only by physicians with specified qualifications.

(7) The package of the drug dispensed to the patient may be required to contain a package insert containing appropriate information for the safe and effective use of the drug by the layman.

(8) The approval of the new drug application may be revoked.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 30, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-12812 Filed 8-14-72;8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 47]

[Docket No. 11271: Reference Notice 71-21]

NOTICE OF OWNERSHIP BY TRANSFEREE OF U.S. REGISTERED AIRCRAFT

Withdrawal of Notice of Proposed Rule Making

The purpose of this notice is to withdraw Notice 71-21 (36 F.R. 14271) in which the Federal Aviation Administration solicited comments on a proposed amendment to Part 47 of the Federal Aviation Regulations that would have required the buyer or other transferee of an aircraft last registered in the United States to notify the FAA of his ownership within 10 days after he becomes the owner, unless within that period he submitted an application for aircraft registration under that part.

Since the issuance of Notice 71-21, further study has revealed that the annual registration eligibility reporting under § 47.44 has resulted in aircraft records being more current and accurate than previously. Consequently, it appears that rule making action on the proposed amendment is no longer appropriate, and that Notice 71-21 should be withdrawn.

The withdrawal of this notice, however, does not preclude the FAA from issuing similar notices in the future nor does it commit the FAA to any course of action.

In consideration of the foregoing, the notice of proposed rule making published in the FEDERAL REGISTER (36 F.R. 14271) on August 3, 1971, and circulated as Notice 71-21, entitled "Notice of Ownership by Transferee of U.S. Registered Aircraft" is hereby withdrawn.

This withdrawal is issued under the authority of section 313(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1354 (a)), and section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Oklahoma City, Okla., on August 3, 1972.

A. L. COULTER,
Director,
Aeronautical Center.

[FR Doc.72-12841 Filed 8-14-72;8:48 am]

National Highway Traffic Safety Administration

[49 CFR Part 571]

[Docket No. 71-7; Notice 3]

TRUCK-CAMPER LOADING

Notice of Proposed Rulemaking

The purpose of this notice is to propose an amendment to 49 CFR 571.126, Motor Vehicle Safety Standard No. 126, Truck-Camper Loading, that would require slide-in campers to be identified by a camper identification number.

Standard No. 126 (37 F.R. 16496) requires each slide-in camper manufactured on or after January 1, 1973, to have a label permanently affixed to it, stating the manufacturer's name, certification of compliance, month and year of manufacture, and certain other information. The NHTSA believes that a camper identification number should be added to the label to facilitate any future defect notification and recall campaigns that might occur, and herewith proposes that campers be identified with a number which, like the vehicle identification number required by Standard No. 115, would not be identical within a 10-year period.

In consideration of the foregoing, it is proposed that 49 CFR 571.126, Motor Vehicle Safety Standard No. 126, be revised by adding paragraph (e) to paragraph S5.1.1 to read as follows:

(e) Slide-in camper identification number: Each manufacturer shall assign a number for identification purposes to each slide-in camper, which shall consist of arabic numerals, roman letters, or both. The slide-in camper identification number of two campers manufactured by a manufacturer within a 10-year period shall not be identical.

Interested persons are invited to submit written data, views or arguments on this proposal. Comments should refer to the docket number and notice number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5219, 400 Seventh Street SW., Washington, DC 20590. It is requested, but not required, that 10 copies be submitted. All comments received before the close of business on September 15, 1972, will be considered, and will be available in the docket at the above address for examination both before and after the closing date. To the extent possible, comments filed after the above date will also be considered by the Administration. However, the rulemaking action may proceed at any time after that date, and comments received after the closing date and too late for consideration in regard to the action will be treated as suggestions for future rulemaking. The Administration will continue to file relevant material, as it becomes available in the docket after the closing date and it is recommended that interested persons continue to examine the docket for new materials.

Proposed effective date: January 1, 1973.

This notice is issued under the authority of sections 103, 112, 114, and 119 of the National Traffic and Motor Vehicle Safety Act of 1966 (15 U.S.C. 1392, 1401, 1403, 1407) and the delegation of authority at 49 CFR 1.51 and 49 CFR 501.8.

Issued on August 3, 1972.

ROBERT L. CARTER,
Associate Administrator,
Motor Vehicle Program.

[FR Doc.72-12811 Filed 8-14-72;8:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing Production and Mortgage Credit—Federal Housing Commissioner (Federal Housing Administration)

[24 CFR Parts 203, 213, 222]

[Docket No. R-72-208]

FHA REQUIREMENT OF FLOOD INSURANCE IN SPECIAL FLOOD HAZARD AREAS

Notice of Proposed Rule Making

The Department of Housing and Urban Development proposes to require flood insurance coverage if property securing a mortgage insured by that Department is located in a special flood hazard area, as designated by the Secretary of HUD, and if the first-floor elevation of the property is less than 1 foot above the specified maximum elevation of such area. To carry out this policy the Department proposes to amend Chapter II of its regulations to require the collection by the mortgagee and the payment by the mortgagor, when the property is located in such areas, of flood insurance premiums.

The proposed amendments would require the inclusion in the mortgage of a