§ 5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

* * * * *

(a) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Director, Office of Biological Product Review, CBER.

(3) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

(b) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(2) The Directors and Deputy Directors of the Office of Drug Evaluation I and Drug Evaluation II, CDER.

(3) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation I and Drug Evaluation II, CDER.

Dated: February 21, 1989.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-4516 Filed 2-27-89; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 357

[Docket No. 87N-0181]

Cholecystokinetic Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends the final monograph for over-the-counter (OTC) cholecystokinetic drug products to include the ingredient hydrogenated soybean oil. FDA is issuing this amenedment of the final monograph after considering public comments on the agency's proposed regulation and all new data and information on OTC cholecystokinetic drug products that have come to the agency's attention. This amendment of the final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: February 28, 1990.

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 10, 1983 (48 FR 27004), FDA issued a final monograph for OTC cholecystokinetic drug products (21 CFR Part 357, Subpart C). The only active ingredient included in the monograph was a 50-percent aqueous emulsion of corn oil.

On March 16, 1984, FDA received a citizen petition (Docket No. 79N-0368/CP) requesting that the final monograph for OTC cholecystokinetic drug products be amended to include a powder dosage form containing hydrogenated soybean oil and lecithin. The citizen petition was supplemented by data contained in letters dated January 14, 1985, November 14, 1985, June 1, 1987, and January 13, 1988. These letters are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, under Docket No. 79N-0368 as LET004, LET006, LET009, and LET011, respectively.

After reviewing the citizen petition and the supplemental data, the agency concluded that there was sufficient evidence to generally recognize hydrogenated soybean oil as safe and effective and not misbranded for use as an OTC cholecystokinetic drug product. The agency's proposed regulation, in the form of a proposed amendment of the final monograph for OTC cholecystokinetic drug products, was published in the Federal Register of August 15, 1988 (53 FR 30786). In that document, the agency proposed to include hydrogenated soybean oil in the final monograph for OTC cholecystokinetic drug products. Interested persons were invited to file by October 14, 1988, written comments or objections before the Commissioner of Food and Drugs regarding the proposal.

In response to the proposed rule, one manufacturer submitted a comment calling the agency's attention to an error in the proposal, i.e., at 53 FR 30786 and 30787 hydrogenated soybean oil was described incorrectly as "partially hydrolyzed" rather than "partially hydrogenated." The agency notes this error, and it has been corrected in this final rule. A copy of the comment is on public display in the Dockets Management Branch (address above). Final agency action occurs with the publication of this final rule amending the monograph for OTC cholecystokinetic drug products.

As discussed in the proposal (53 FR 30786), the agency advised that any final rule resulting from the proposal would be effective 12 months after its date of publication in the Federal Register. Therefore, on or after February 28, 1990, any OTC drug product that is not in compliance may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date that the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (53 FR 30786). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC cholecystokinetic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC cholecystokinetic drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact, and the evidence

supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

List of Subjects in 21 CFR Part 357

Cholecystokinetic drug products, Labeling, Over-the-counter drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended in Part 357 as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 357 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553, 21 CFR 5.10 and 5.11.

2. Section 357.210 is revised to read as follows:

§ 357.210 Cholecystokinetic active ingredients.

The active ingredient of the product consists of any of the following when used within the specified concentration and dosage form established for each ingredient:

(a) 50-percent aqueous emulsion of corn oil.

(b) Hydrogenated soybean oil in a suitable, water-dispersible powder. The hydrogenated soybean oil is food-grade, partially hydrogenated with a melting point of 41 to 43.5 °C, an iodine value of 65 to 69, and a fatty acid composition as follows:

Fatty acid	Percent composition
Myristic acid	0.1
Palmitic acid	10.0
Palmitoleic acid	0.1
Stearic acid	13.5
Oleic acid	72.0
Linoleic acid	3.8
Linolenic acid	0.1
Arachidic acid	0.5
Behenic acid	0.2

3. Section 357.250 is amended by revising paragraphs (d)(2) and (3) to read as follows:

§ 357.250 Labeling of cholecystokinetic drug products.

* * * * *

(d) * * *

(2) *For products containing 50-percent aqueous emulsion of corn oil.*

(i) "Shake well before using."

(ii) Oral dosage is 60 milliliters 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(3) *For products containing hydrogeneated soybean oil.* Oral dosage is 12.4 grams in a suitable, water-dispersible powder in 2 to 3 ounces of water. Stir briskly to prepare a suspension before using. Drink 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

* * * * *

4. Section 357.280 is revised to read as follows:

§ 357.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following information for ingredients identified in § 357.210: *Indication.* "For visualization of biliary ducts during cholecystography."

Dated: December 23, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 89-4613 Filed 2-27-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

Office of the Assistant Secretary for Community Planning and Development

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Parts 15, 24, 203, 234, 510, 511, 570, 885, 904, 941, and 2002

[Docket No. N-89-1945]

Announcement of Effective Dates

AGENCY: Office of the Secretary; Office of the Assistant Secretary for Housing—Federal Housing Commissioner; Office of the Assistant Secretary for Community Planning and Development; Office of the Assistant Secretary for Public and Indian Housing; HUD.

ACTION: Notice of announcement of effective dates for certain recent final rules.

SUMMARY: Section 7(o)(3) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(o)(3), requires HUD to wait thirty calendar days of continuous session of Congress, after publication, before it makes a published rule effective. Thirty calendar days of continuous session of Congress have now expired in the present Congress since these rules were published. This notice announces the effective dates for certain recently published final rules. For an explanation of subject matter on the rules, see **"SUPPLEMENTARY INFORMATION".**

DATES: For effective dates, see **"SUPPLEMENTARY INFORMATION."**

FOR FURTHER INFORMATION CONTACT: Grady J. Norris, Assistant General Counsel for Regulations, Department of Housing and Urban Development, Room 10276, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 755-7055. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The effective date provision of each of the published rules affected by this Notice stated that the rule would become effective upon expiration of the first period of 30 calendar days of continuous session of Congress after publication, and announced that future notice of the rule's effectiveness would be published in the **Federal Register.** Thirty calendar days of continuous session of Congress will have expired in the present Congress before March 3, 1989.

Accordingly, the purpose of this notice is to announce the effective dates for the rules listed below, as follows:

1. *24 CFR Parts 15 and 2002:* The Freedom of Information Reform Act of 1988; Fee Schedule and Fee Waiver Regulations, Final Rule published September 27, 1988 (53 FR 37546), Docket No. R-88-1348; FR-2362.

DATE: Effective Date: March 3, 1989.

2. *24 CFR Part 24:* Debarment Suspension and Limited Denial of Participation, Contractors and Participants, Final Rule published November 15, 1988 (53 FR 45903), Docket No. R-88-831; FR-1676.

DATE: Effective Date: March 3, 1989.

3. *24 CFR Parts 203 and 234:* Disclosure of Annual Rate Changes of Adjustable Rate Mortgages (ARMs) and Carryovers, Final Rule published January 4, 1989 (54 FR 110), Docket No. R-88-1427; FR-2542.

DATE: Effective Date: March 31, 1989.

4. *24 CFR Part 510:* Section 312 Rehabilitation Loan Program; Removal of Risk Premium and Application Fee Provisions, Final Rule published

October 31, 1988 (53 FR 43865), Docket No. R–88–1414; FR–2553.

DATE: Effective Date: March 3, 1989.

5. *24 CFR Part 511:* Rental Rehabilitation Grants, Final Rule published December 6, 1988 (53 FR 49138), Docket No. R–88–1401; FR–2472.

DATE: Effective Date: March 3, 1989.

6. *24 CFR Part 570:* Urban Development Action Grant (UDAG) Application from Consortia of Small Cities, Final Rule published December 28, 1988 (53 FR 52414), Docket No. R–88–1374; FR–2381.

DATE: Effective Date: March 3, 1989.

7. *24 CFR Part 885:* Loans for Housing for the Elderly or Handicapped, Final Rule published November 9, 1988 (53 FR 45265), Docket No. R–88–1391; FR–2477.

DATE: Effective Date: March 3, 1989.

8. *24 CFR Parts 904 and 941:* Public Housing Development; Cost Containment, Final Rule published October 24, 1988 (53 FR 41597), Docket No. R–88–1299; FR–2191).

DATE: Effective Date: March 3, 1989.

Authority: Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: February 22, 1989.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 89–4577 Filed 2–27–89; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 701

[SECNAV Instruction 5211.5C]

Availability of Department of the Navy Records and Publications of the Navy Documents Affecting the Public

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is publishing as a final rule a new specific exemption that will allow the Navy to exempt a new system of records from certain provisions of the Privacy Act of 1974. This new final specific exemption will preclude individuals from accessing the disclosure accounting provision of the Privacy Act as well as individual access to the record system.

EFFECTIVE DATE: February 28, 1989.

FOR FURTHER INFORMATION CONTACT: Mrs. Gwen Aitken, Head, PA/FOIA Branch, Office of the Chief of Naval Operations (OP–09B30), Department of the Navy, The Pentagon, Washington, DC 20350.

SUPPLEMENTARY INFORMATION: On June 13, 1988, at 53 FR 22027 of the **Federal Register**, the Department of the Navy published a proposed exemption rule for a new system of records identified as N01754–3, entitled "Navy Child Development Services Program" under the provisions of 5 U.S.C. 552a(k)(2) of the Privacy Act of 1974. No comments were received. Therefore the Navy is adopting the proposed exemption rule as a final rule.

List of Subjects in 32 CFR Part 701

Privacy Act Exemptions.

For the reasons set forth in the preamble, 32 CFR Part 701 is amended as follows:

Subpart G—Privacy Act Exemptions

1. The authority citation continues to read as follows:

Authority: 5 U.S.C. 552a, 32 CFR Part 286a.

2. Add paragraph (b)(7) to § 701.119.

§ 701.119 Exemptions for specific Navy record systems.

* * * * *

(b) Naval Military Personnel Command.

* * * * *

(7) ID–N01754–3.

System Name. Navy Child Development Services Program

Exemption. Portions of this system of records are exempt from the following subsections of Title 5 U.S.C. 552a (c)(3) and (d).

Authority. 5 U.S.C. 552a(k)(2).

Reasons. Exemption is needed in order to encourage persons having knowledge of abusive or neglectful acts toward children to report such information, and to protect such sources from embarrassment or recriminations, as well as to protect their right to privacy. It is essential that the identities of all individuals who furnish information under an express promise of confidentiality be protected. Additionally, granting individuals access to information relating to criminal and civil law enforcement, as well as the release of certain disclosure accountings, could interfere with ongoing investigations and the orderly administration of justice, in that it could result in the concealment, alteration, destruction, or fabrication of information; could hamper the identification of offenders and the disposition of charges; and could jeopardize the safety and well being of parents and their children.

* * * * *

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

February 21, 1989.

[FR Doc. 89–4606 Filed 2–27–89; 8:45 am]

BILLING CODE 3810–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[FRL–3527–7; KY–050]

Designation of Areas for Air Quality Planning Purposes; Kentucky: Redefinition of Attainment Areas From Rest of State to County-by-County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA today is changing the description of total suspended particulate, sulfur dioxide, carbon monoxide, and ozone attainment areas in the Commonwealth of Kentucky at the request of the Kentucky Natural Resources and Environmental Protection Cabinet. Attainment status designations included in 40 CFR 81.318 will now be listed on a county-by-county basis rather than under the generally inclusive term "Rest of State." This change is anticipated to make it easier for Kentucky to track increment consumption in connection with the prevention of significant deterioration of air quality.

DATES: This action will become effective on May 1, 1989, unless notice is received by March 30, 1989, that someone wishes to submit adverse or critical comments.

ADDRESSES: Written comments on this action should be addressed to Pamela Adams at the EPA Regional Office address listed below. Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations:

Environmental Protection Agency, Region IV, Air Programs Branch, 345 Courtland Street, NE., Atlanta, Georgia 30365.

Kentucky Natural Resources and Environmental Protection Cabinet, Division for Air Quality, 18 Reilly Road, Frankfort Office Park, Frankfort, Kentucky 40601.

FOR FURTHER INFORMATION CONTACT: Pamela Adams, EPA Region IV Air Programs Branch, at the Atlanta addres