

Proposed Rules

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Tuesday, November 17, 2009

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

RIN 0563-AC10

Common Crop Insurance Regulations; Apple Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Notice of reopening of comment period.

SUMMARY: The Federal Crop Insurance Corporation is reopening and extending the comment period for the proposed rule published in the **Federal Register** on Tuesday, September 8, 2009. The proposed rule amends the Common Crop Insurance Regulations, Apple Crop Insurance Provisions to provide policy changes, to clarify existing policy provisions to better meet the needs of insured producers, and to reduce vulnerability to program fraud, waste, and abuse. During the comment period, FCIC received comments that due to the public comment period overlapping with the apple harvest in some areas, sixty days was not adequate to properly review the proposed changes. FCIC agrees additional time is appropriate to ensure all interested persons have time to fully review the proposed rule and provide meaningful comments.

DATES: The comment period for the proposed rule published on September 8, 2009, (73 FR 46023) is reopened. Written comments and opinions on this rule will be accepted until close of business December 17, 2009 and will be considered when the rule is to be made final.

ADDRESSES: Interested persons are invited to submit comments, titled "Apple Crop Provisions", by any of the following methods:

- *By Mail to:* Director, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility—Mail Stop 0812, Room 421, PO

Box 419205, Kansas City, MO 64141-6205.

- *By Express Mail to:* Director, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility, Stop 0812, 9240 Troost Avenue, Kansas City, MO 64131-3055.

- *E-Mail:* DirectorPDD@rma.usda.gov.
- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

A copy of each response will be available for public inspection and copying from 7 a.m. to 4:30 p.m., CST, Monday through Friday, except holidays, at 6501 Beacon Drive, Stop 0812, Room 421, Kansas City, MO 64133-4676.

FOR FURTHER INFORMATION CONTACT: Erin Albright, Risk Management Specialist, Product Management, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility, Stop 0812, Room 421, PO Box 419205, Kansas City, MO 64141-6205, telephone (816) 926-7730.

SUPPLEMENTARY INFORMATION:

Background

On Tuesday, September 8, 2009, FCIC published a proposed rule in the **Federal Register**. The proposed rule amends the Common Crop Insurance Regulations, Apple Crop Insurance Provisions to provide policy changes, to clarify existing policy provisions to better meet the needs of insured producers, and to reduce vulnerability to program fraud, waste, and abuse.

The proposed rule public comment period of 60 days ended on November 9, 2009. Based on several requests received during the comment period, FCIC is reopening and extending the comment period until December 17, 2009. This action will allow interested persons additional time to prepare and submit comments regarding the proposed rule.

Signed in Washington, DC, on November 10, 2009.

William J. Murphy,
Manager, Federal Crop Insurance Corporation.

[FR Doc. E9-27595 Filed 11-16-09; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-333P]

Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance carisoprodol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and on an evaluation of the relevant data by DEA. If finalized, this action would impose the regulatory controls and criminal sanctions of schedule IV on those who handle carisoprodol and products containing carisoprodol.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before December 17, 2009. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Standard Time (EST) on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-333" on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to the Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this

document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight EST on the day the comment period closes because <http://www.regulations.gov> terminates the public's ability to submit comments at midnight EST on the day the comment period closes. Commenters in time zones other than EST may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT:

Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Comments and Requests for Hearing: In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (5 U.S.C. 556 and 557). All persons are invited to submit their comments or objections with regard to this proposal. Requests for a hearing may be submitted by interested persons and must conform to the requirements of 21 CFR 1308.44 and 1316.47. The request should state, with particularity, the issues concerning which the person desires to be heard and the requestor's interest in the proceeding. Only interested persons, defined in the regulations as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," may request a hearing. 21 CFR 1308.42. Please note that DEA may grant a hearing only "for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment, or repeal of a rule issuable" pursuant to 21 U.S.C. 811(a). All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov>

and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

Carisoprodol is a centrally acting muscle relaxant and is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions. Carisoprodol has been available since 1959 as a prescription drug in the United States under the trade name Soma®. It is also marketed as generic products. Carisoprodol is similar to a variety of central nervous system (CNS) depressants, including meprobamate (C-IV) and chlorthalidoxepoxide (C-IV). The actual abuse data from several databases demonstrate that carisoprodol is abused in the United States. Because of growing concerns about abuse of carisoprodol, a number of states have regulated

carisoprodol under their controlled substance regulations, and a number of additional states are currently considering such regulation.

Because of the evidence relating to diversion, abuse, and trafficking of carisoprodol, in March 1996, the DEA requested from the DHHS a scientific and medical evaluation and a scheduling recommendation for carisoprodol, in accordance with 21 U.S.C. 811(b).

In February 1997, the U.S. Food and Drug Administration (FDA) Drug Abuse Advisory Committee (DAAC) deliberated upon the abuse and scheduling issues and concluded that the data were insufficient to control carisoprodol under the CSA at that time. Since the FDA DAAC meeting, pharmacological studies addressing the abuse liability of carisoprodol have been conducted under the direction of the National Institute on Drug Abuse (NIDA) and the College on Problems of Drug Dependence (CPDD). DEA acquired new carisoprodol-related data on actual abuse, law enforcement encounters and other information and sent this supplementary information to DHHS on November 14, 2005. FDA acquired new data from the Drug Abuse Warning Network (DAWN), National Survey on Drug Use and Health (NSDUH), Florida Medical Examiners Commission reports, FDA's Adverse Event Reporting System (AERS) and information from the published scientific literature and conducted a scientific and medical evaluation. These data collectively indicate that carisoprodol has abuse potential and is being diverted, trafficked, with increasing frequency and magnitude.

Carisoprodol abuse has been associated with increasing numbers of emergency department (ED) visits in recent years as indicated by DAWN. The "abuse frequency," calculated as ED visits per 10,000 prescriptions, of carisoprodol (frequency range during 2002-2007: 15.1 to 22.6 visits/10,000 prescriptions) is similar to that of a schedule IV drug, diazepam (frequency range during 2002-2007: 12.5 to 14.1 visits/10,000 prescriptions). Carisoprodol is used as either the sole drug or in combination with other substances such as opioids, benzodiazepine, alcohol, marijuana, and cocaine. Data from the AERS database show that carisoprodol is associated with adverse health events including dependence and withdrawal syndrome.

The data from National Poison Data System of the American Association of Poison Control Centers documented 8,821 carisoprodol toxic exposure cases including 3,605 cases in which it was

the sole drug mentioned in 2007. Medical Examiners Commission Reports released by the Florida Department of Law Enforcement (FDLE) indicate that carisoprodol/meprobamate related deaths in Florida increased by 100 percent from 208 deaths in 2003 to 415 deaths in 2008.

The National Forensic Laboratory Information System (NFLIS), a DEA system that tracks analyzed drug exhibits submitted by the federal, state, and local law enforcement, documented evidence of substantial diversion of carisoprodol. For example, law enforcement submitted a total of 3,873 carisoprodol drug items to participating forensic laboratories in 2008. NFLIS consistently listed carisoprodol in the top 25 most frequently identified drugs since 2000. The 2007 NSDUH data show that 2.7 million individuals used Soma® in their lifetime (i.e., ever used) for a non-medical purpose.

The data from *in vitro* electrophysiological studies using the whole-cell patch clamp technique demonstrate that carisoprodol elicits barbiturate-like effects. Intravenous drug self-administration studies in rhesus monkeys show that carisoprodol has positive reinforcing effects. Meprobamate, pentobarbital, and chlordiazepoxide substitute fully for the discriminative stimulus effects of carisoprodol in rats. Bemegride, a barbiturate antagonist, antagonizes the discriminative stimulus effects of carisoprodol.

Data from an animal study indicates that carisoprodol has dependence liability similar to barbital (schedule IV), a central nervous system depressant. Carisoprodol administered orally fully prevented the appearance of abstinence phenomena in dogs tolerant and dependent on barbital. Several published reports document evidence of tolerance and dependence to carisoprodol and indicate the occurrence of abstinence symptoms during carisoprodol withdrawal in humans.

On October 6, 2009, the Acting Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that carisoprodol be placed into schedule IV of the CSA. Enclosed with the October 6, 2009, letter was a document prepared by the FDA entitled, "Basis for the Recommendation for Control of Carisoprodol in Schedule IV of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)). The factors considered by the Assistant

Secretary of Health and DEA 21 U.S.C. 811(c)) with respect to carisoprodol were:

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effects;
- (3) The state of current scientific knowledge regarding the drug;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Based on the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

1. Carisoprodol has a low potential for abuse relative to the drugs or other substances in Schedule III. Animal studies indicate that carisoprodol is similar to schedule IV drugs such as meprobamate and chlordiazepoxide in its central nervous system depressant effects. The documented data on law enforcement encounters and actual abuse of carisoprodol demonstrate that it has a potential for abuse and is being diverted and abused. Since 2000, DEA's NFLIS database consistently mentioned carisoprodol in the top 25 drugs that were most frequently identified by state and local forensic laboratories thereby indicating that carisoprodol is being diverted. Emergency department visits data from DAWN indicate that abuse frequency of carisoprodol is similar to that of diazepam, a schedule IV drug. Recent data from DAWN medical examiner reports and emergency department visits showed an increase in carisoprodol abuse.

2. Carisoprodol has a currently accepted medical use in treatment in the United States. Carisoprodol is an FDA approved drug and is used for the relief of discomfort associated with acute, painful musculoskeletal conditions.

3. Abuse of carisoprodol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. Carisoprodol, similar to barbital (schedule IV), prevents the abstinence syndrome in drug withdrawn barbital-dependent dogs. Published

reports indicate that carisoprodol causes psychological or physical dependence and withdrawal syndrome.

Based on these findings, the Deputy Administrator of DEA concludes that carisoprodol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible warrants control in schedule IV of the CSA. (21 U.S.C. 812(b)(4))

References to the above studies and data may be found in the Health and Human Services scheduling recommendation and DEA's independent analysis, both of which are available on the electronic docket associated with this rulemaking.

Requirements for Handling Carisoprodol

If this rule is finalized as proposed, carisoprodol would be subject to CSA regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule IV controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with carisoprodol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with carisoprodol, would need to be registered to conduct such activities in accordance with 21 CFR part 1301.

Security. Carisoprodol would be subject to schedules III–V security requirements and would need to be manufactured, distributed, and stored in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77.

Labeling and Packaging. All labels and labeling for commercial containers of carisoprodol which are distributed on or after finalization of this rule would need to comply with requirements of 21 CFR 1302.03–1302.07.

Inventory. Every registrant required to keep records and who possesses any quantity of carisoprodol would be required to keep an inventory of all stocks of carisoprodol on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who desires registration in schedule IV for carisoprodol would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants would be required to keep records pursuant to 21

CFR 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23.

Prescriptions. All prescriptions for carisoprodol or prescriptions for products containing carisoprodol would be required to be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21, 1306.22–1306.27.

Importation and Exportation. All importation and exportation of carisoprodol would need to be in compliance with 21 CFR part 1312.

Criminal Liability. Any activity with carisoprodol not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after finalization of this proposed rule would be unlawful.

Regulatory Certifications

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

In considering the impact on small entities, the first question is whether a substantial number of small entities are affected. In this instance, the entities affected are those now selling carisoprodol-containing products without registration. DEA has identified 22 firms manufacturing carisoprodol-containing products in 2009.¹ Fifteen of these firms have existing DEA registrations. This leaves seven firms from this data set selling carisoprodol without registration. DEA has no information on the number of non-registrants distributing or importing carisoprodol, but there is every reason to believe that the number of such firms is well in excess of the seven already identified. The Small Business Administration size standard for a small wholesaler of drugs is 100 employees. It is clearly possible to operate a drug distributing firm with fewer than 100

employees. There can be no question that a substantial number of small entities will be affected by this rule.

The impact on non-registrants now selling carisoprodol will occur in two forms: the cost of registration and the cost of meeting the security requirements in 21 CFR part 1301. There is also a potential impact on firms not now selling carisoprodol who might have wished to enter the market.

The annual registration fee for a distributor, importer, or exporter is \$1,147. There is some uncertainty in estimating the cost of meeting the security requirements, because most nonregistrants already meet the security requirements, at least in part, for schedule III and IV substances. To be conservative, it is assumed that every nonregistrant will have to buy a safe to store carisoprodol. A safe with capacity of 13.5 cubic feet should be adequate. A safe of this size may be purchased for \$1,350.² Annualized over 15 years at 7.0 percent, that is \$148 per year. Total annual cost of compliance with the rule, then, is \$1,295. The usual standard for a significant economic impact is 1.0 percent of revenue. For \$1,295 per year to be a significant economic impact, annual revenue of a firm would have to be under \$130,000. Any firm in the business of distributing drugs needs annual revenue well in excess of that amount to sustain itself.

It should be acknowledged that, for a small firm, there may be some inconvenience and expense in preparing necessary forms for registration and registration renewal. These are minor costs. There are also recordkeeping requirements, but these impose little or no incremental cost for a firm that is already maintaining records needed for a wholesale business. The costs of registration and security requirements will not be a significant economic impact.

If a firm chose not to register and to drop its carisoprodol line, the cost to the firm would exceed its earnings on the carisoprodol sales. The firm might also lose some customers who do not want to buy from a vendor without carisoprodol in its product line. A competent manager will recognize this cost. In light of the very small cost of registering, he would presumably choose to drop carisoprodol from the firm’s products only if the firm were earning a negligible profit from that line and he judged that dropping it would not turn away significant customers. In light of the foregoing analysis, DEA

finds that this rule will not have a significant economic impact on a substantial number of small entities. DEA has no information regarding the number of persons who may distribute carisoprodol-containing products, but do not manufacture, package, repackage, or relabel those products. Therefore, DEA seeks comment on any entities that might be affected by this control action.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator

² Nationwide Safes.com <http://www.nationwidesafes.com/capacity-more-than-4pt0-cu-ft.html>.

¹ IMS Health National Prescription Audit (NPA).

hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by redesignating paragraphs (c)(5) through (c)(52) as paragraphs (c)(6) through (c)(53) and adding a new paragraph (c)(5) to read as follows:

§ 1308.14 Schedule IV.

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(c) * * *

(5) Carisoprodol 8192
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Dated: November 10, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9-27583 Filed 11-16-09; 8:45 am]

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