(2) *Turkeys*—

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 170.3	.....	Growing turkeys: For prevention and control of coccidiosis.	Feed continuously as sole ration. For turkeys grown for meat purposes only. Do not feed to laying birds.	054771
(ii) 113.5 to 170.3	Bacitracin methylene disalicylate 4 to 50.	Growing turkeys: For prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration until 14 to 16 weeks of age. For turkeys grown for meat purposes only. Do not feed to laying birds.	054771

Dated: February 3, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–02617 Filed 2–26–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–370]

Schedules of Controlled Substances: Placement of Alfaxalone into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places the substance 5α-pregnan-3α-ol-11,20-dione (alfaxalone), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle alfaxalone and substances containing alfaxalone.

DATES: *Effective Date:* March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed . . ..'' Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of the DEA. 28 CFR 0.104.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action is based on a recommendation from the Assistant Secretary of the HHS and on an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle or propose to handle alfaxalone.

Background

Alfaxalone (5α-pregnan-3α-ol-11,20-dione, previously spelled ''alphaxalone''), a substance with central nervous system (CNS) depressant properties, is a neurosteroid that is a derivative of 11-alpha-hydroxy-progesterone. On October 23, 2012, the Food and Drug Administration (FDA) published a final rule to approve a New Animal Drug Application (NADA, 141–342) for alfaxalone (Alfaxan®), as an intravenous injectable anesthetic, for the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance of anesthesia with an inhalant anesthetic, in cats and dogs (77 FR 64715). Alfaxalone primarily acts as an agonist at the gamma-aminobutyric acid (GABA) receptor-channel complex, with a mechanism of action at this site similar to that of barbiturates like phenobarbital (schedule IV) and methohexital (schedule IV), benzodiazepines such as diazepam (schedule IV) and midazolam (schedule IV), as well as the anesthetic agents

[1] As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1995. In addition, because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this document, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

propofol (proposed to be controlled as a schedule IV substance, 75 FR 66195, Oct. 27, 2010) and fospropofol (schedule IV).

HHS and DEA Eight-Factor Analyses

On July 17, 2012, the Assistant Secretary of the HHS provided to the DEA a scientific and medical evaluation and scheduling recommendation entitled ''Basis for the Recommendation to Control Alfaxalone in Schedule IV of the Controlled Substances Act.'' After considering the eight factors in 21 U.S.C. 811(c), including consideration of the substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that alfaxalone be controlled in schedule IV of the CSA under 21 U.S.C. 812(b). In response, the DEA conducted its own eight-factor analysis of alfaxalone pursuant to 21 U.S.C. 811(c). Both the DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA–370) at *www.regulations.gov* under ''Supporting and Related Material.''

Determination to Schedule Alfaxalone

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from the HHS, the Administrator of the DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Placement of Alfaxalone into Schedule IV'' which proposed placement of alfaxalone in schedule IV of the CSA. 78 FR 17895, March 25, 2013. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations by April 24, 2013. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before April 24, 2013.

Comments Received

The DEA received four comments on the proposed rule to schedule alfaxalone. Two commenters were in favor of controlling alfaxalone as a schedule IV controlled substance. One commenter was in favor of controlling alfaxalone as a schedule V controlled substance rather than a schedule IV controlled substance, and one commenter opposed the control of alfaxalone.

Support of the Proposed Rule:

Two commenters supported controlling alfaxalone as a schedule IV controlled substance. These commenters indicated support for controlling alfaxalone under the CSA based on the abuse potential of the substance. Because alfaxalone is indicated for use as a pre-anesthetic and anesthetic in cats and dogs, these commenters felt that the abuse potential was particularly high for persons with access to the substance in the medical field. One commenter noted that controlling alfaxalone as a schedule IV controlled substance is appropriate because it could be abused in a manner similar to other schedule IV CNS depressants. The commenters believe that controlling alfaxalone as a schedule IV controlled substance will provide the necessary controls to prevent its diversion.

DEA Response: The DEA appreciates the comments in support of this rulemaking.

Opposition to the Proposed Rule:

Two commenters opposed the proposal to control alfaxalone as a schedule IV controlled substance.

Request Not to Control Alfaxalone:

One commenter opposed controlling alfaxalone at all and stated that alfaxalone does not have the same abuse potential as Xanax® (alprazolam) (schedule IV), Valium® (diazepam) (schedule IV), and other benzodiazepines. The commenter also stated that controlling alfaxalone under the CSA would make it difficult for veterinarians and animal surgeons to acquire the drug. Lastly, this commenter stated that alfaxalone is ''unheard of outside of the veterinary community and does not have a 'black market' as do the other schedule IV drugs.''

DEA Response: The DEA does not agree. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed * * *.'' This scheduling action was initiated when the DEA received a scientific and medical evaluation and a scheduling recommendation to control alfaxalone as a schedule IV controlled substance from the Assistant Secretary of the HHS. In accordance with 21 U.S.C. 811(c), the DEA conducted its own analysis of the eight factors determinative of control or removal: (1) Its actual or relative potential for abuse; (2) scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the drug or other substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significant 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. The summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in this scheduling action, was provided in the proposed rule. Both the DEA and the HHS analyses have been made available in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *www.regulations.gov* under Docket Number DEA–370.

Based on the review of the HHS evaluation and scheduling recommendation and all other relevant data, the DEA found that alfaxalone has an abuse potential similar to other schedule IV drugs, including the benzodiazepines diazepam and midazolam, the barbiturates phenobarbital and methohexital, and also the anesthetic agents propofol (proposed to be controlled as a schedule IV substance, 75 FR 66195, Oct. 27, 2010) and fospropofol. Alfaxalone also acts as an agonist at the gamma-aminobutyric acid (GABA) receptor-channel complex, with a mechanism of action at the site similar to that of benzodiazepines like diazepam(schedule IV) and midazolam (schedule IV). This mechanism of action is also similar to that of other schedule IV controlled substances, including barbiturates like phenobarbital and methohexital, and also anesthetic agents like propofol (proposed to be controlled as a schedule IV substance, 75 FR 66195, Oct. 27, 2010) and fospropofol. It should be noted that alfaxalone's current exclusive use as a veterinary anesthetic drug and the asserted conclusion that there is no ''black market'' for the substance, do not negate its abuse potential and associated risk of diversion. The DEA and HHS analyses demonstrate that alfaxalone does have the potential for abuse and meets the necessary findings on potential for abuse, currently accepted medical use, and physical or psychological dependence for placement in schedule IV.

Burdens associated with acquiring a substance as a result of control under the CSA are not relevant factors to the determination whether a substance should be controlled or under what schedule a substance should be placed if it is controlled. *See* 21 U.S.C. 811 and 812. Nonetheless, the DEA disagrees with the unsupported statement that making alfaxalone a controlled substance would make it difficult for veterinarians and animal surgeons to

acquire the drug. Several other anesthetic substances used by veterinarians and other practitioners are controlled under the CSA. All veterinarians and animal surgeons who are authorized by the State in which they practice to handle alfaxalone and who are registered with the DEA to dispense controlled substances may acquire alfaxalone once it is controlled. As discussed in the Regulatory Flexibility Analysis section of this document, currently 98% of DEA registrants (most of which are small businesses) are already authorized to handle schedule IV controlled substances.

Request to Control Alfaxalone as a Schedule V Substance:

One commenter stated that alfaxalone should be controlled as a schedule V controlled substance. This commenter stated that there was limited information available regarding alfaxalone's abuse. The commenter also stated that alfaxalone is a new introduction to the United States veterinary market, and controlling it in the least stringent schedule, schedule V, would minimize burdens on practitioners using it for legitimate purposes, while also imposing controls to account for its abuse potential.

DEA Response: The DEA does not agree. The DEA thoroughly reviewed the scientific and medical evaluation and the scheduling recommendation to control alfaxalone as a schedule IV controlled substance from the HHS.

Additionally, the DEA conducted its own analysis of the eight factors in accordance with 21 U.S.C. 811(b) and made the findings required under 21 U.S.C. 812(b) for the placement of alfaxalone in schedule IV. Based on the review of the HHS's evaluation and scheduling recommendation and all other relevant and available data, the DEA found that alfaxalone has an abuse potential similar to other schedule IV controlled substances, including the benzodiazepines diazepam and midazolam, barbiturates phenobarbital and methohexital, and also the anesthetic agents propofol (proposed to be controlled as a schedule IV substance, 75 FR 66195, Oct. 27, 2010) and fospropofol.

While not relevant to the substance's schedule placement, the DEA does not agree with this commenter's concern that the requirements applicable to schedule IV controlled substances are more burdensome than the requirements applicable to schedule V controlled substances. There are only very minimal differences in handling requirements between schedule IV and schedule V controlled substances. Most importantly for purposes of responding to this comment, the physical security requirements for schedule IV and V controlled substances are the same. Also, under the CSA, schedule V controlled substances may be dispensed without a prescription, while schedule IV controlled substances may only be dispensed pursuant to a prescription. However, this distinction is of no consequence with regard to alfaxalone because alfaxalone cannot be prescribed by a veterinarian, nor may alfaxalone be dispensed by a pharmacist pursuant to a prescription. Federal law restricts this drug to use by or on the order of a licensed veterinarian (i.e., it may only be administered). 21 CFR 522.52; *see also* 21 CFR 514.8.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of alfaxalone. As such, the DEA is scheduling alfaxalone as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) 5α-pregnan-3α-ol-11,20-dione (alfaxalone) has a low potential for abuse relative to the drugs or other substances in schedule III; the overall abuse potential of alfaxalone is comparable to the schedule IV controlled substances diazepam, midazolam, phenobarbital, methohexital, propofol (proposed to be controlled as a schedule IV substance, 75 FR 66195, Oct. 27, 2010), and fospropofol;

(2) 5α-pregnan-3α-ol-11,20-dione (alfaxalone) has a currently accepted medical use in treatment in the United States; alfaxalone was approved for marketing by the FDA as a veterinary anesthetic product for the induction and maintenance of anesthesia in cats and in dogs; and

(3) Abuse of 5α-pregnan-3α-ol-11,20-dione (alfaxalone) may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

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

Requirements for Handling Alfaxalone

Upon the effective date of this final rule, any person who handles alfaxalone is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engagement in research, and conduct of instructional activities, of schedule IV controlled substances including the following:

Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) alfaxalone, or who desires to handle alfaxalone, must be registered with the DEA to conduct such activities, pursuant to 21 U.S.C. 822, 823, 957 and 958, and in accordance with 21 CFR parts 1301 and 1312 as of March 31, 2014. Any person who currently handles alfaxalone and is not registered with the DEA must submit an application for registration and may not continue to handle alfaxalone as of March 31, 2014 unless the DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

Security. Alfaxalone is subject to schedule III–V security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b) and in accordance with 21 CFR 1301.71–1301.93, as of March 31, 2014.

Labeling and Packaging. All labels and labeling for commercial containers of alfaxalone must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302, as of March 31, 2014.

Inventory. Every DEA registrant who possesses any quantity of alfaxalone on the effective date of this final rule must to take an inventory of all stocks of alfaxalone on hand as of March 31, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who becomes registered with the DEA after March 31, 2014 must take an initial inventory of all stocks of controlled substances (including alfaxalone) on hand on the date the registrant first engages in the handling

of controlled substances, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including alfaxalone) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Records. All DEA registrants must maintain records with respect to alfaxalone pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1307, and 1312, as of March 31, 2014.

Prescriptions. The DEA recognizes that alfaxalone is currently only approved as an injectable anesthetic that is administered to patients. The DEA also acknowledges that Federal law currently restricts alfaxalone to use by or on the order of a licensed veterinarian, and it may not be dispensed pursuant to a prescription. 21 CFR 522.52; *see also* 21 CFR 514.8. A ''prescription'' is defined as an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription). 21 CFR 1300.01(b). However, any lawful prescriptions for alfaxalone or prescriptions for products containing alfaxalone must comply with 21 U.S.C. 829 and must be issued in accordance with 21 CFR parts 1306 and 1311 subpart C as of March 31, 2014.

Importation and Exportation. All importation and exportation of alfaxalone must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312 as of March 31, 2014.

Criminal Liability. Any activity involving alfaxalone not authorized by, or in violation of, the CSA, occurring as of March 31, 2014 is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

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 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. The rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this final rule is to place alfaxalone, including its salts, isomers, and salts of isomers, into schedule IV of the CSA. By this final rule, alfaxalone will remain in schedule IV unless and until additional scheduling action is taken to either transfer it between the schedules or to remove it from the list of schedules. *See* 21 U.S.C. 811 and 812. No less restrictive measures (i.e., no control or control in schedule V) enable the DEA to meet its statutory obligations under the CSA.

On September 6, 2012, the FDA approved for use in the United States one product containing alfaxalone, which will have FDA marketing exclusivity and patent protection for several years. Accordingly, the number of currently identifiable manufacturers, distributors, importers, and exporters for alfaxalone is extremely small. The manufacturer who obtained FDA approval for the sale of alfaxalone product in the United States is not considered a ''small entity'' in accordance with the RFA and Small Business Administration (SBA) size standards. Upon expiration of the exclusivity period, and more likely, the related patent, additional products containing alfaxalone may receive approvals from the FDA, and thus additional manufacturers, distributors, importers, and exporters will handle alfaxalone. Whether such manufacturers, distributors, importers, or exporters may qualify as small entities cannot be determined at this time.

There are currently approximately 1.5 million controlled substance registrations, representing approximately 381,000 entities. The DEA estimates that 371,000 (97%) of these entities are considered ''small entities'' in accordance with the RFA and SBA size standards. 5 U.S.C. 601(6) and 15 U.S.C. 632. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the dispensing rates of new chemical entities, the DEA is unable to determine the number of small entities which might handle alfaxalone. However, because alfaxalone is a new chemical entity that is a veterinary anesthetic administered in veterinary settings and is not prescribed to ultimate users, the number of entities affected by the rule would be far fewer than the 381,000 entities represented by all DEA registrants. There are approximately 66,361 veterinarian practitioners and 23 veterinarian distributors (schedules III–V) registered with the DEA.

Despite the fact that the number of small entities possibly impacted by this rule could not be determined, the DEA concludes that they would not experience a significant economic impact as a result of this rule. The DEA estimates all anticipated alfaxalone handlers to be DEA registrants, and currently 98% of DEA registrants (most of which are small entities) are authorized to handle schedule IV controlled substances. Even assuming that all of these registrants were to handle alfaxalone (e.g., practitioners administer the substance), the costs that they would incur as a result of alfaxalone's scheduling would be nominal.

Registrants that dispense (e.g., administer) alfaxalone are expected to incur nominal additional security, inventory, and recordkeeping costs. These registered entities have already established and implemented the systems and processes required to handle schedule IV controlled

substances and can easily absorb the costs of administering alfaxalone with nominal to no additional economic burden. For example, because DEA-veterinary practitioners are likely to already be schedule IV handlers, they already secure schedule II–V controlled substances in a securely locked, substantially constructed cabinet. See 21 CFR 1301.75(b). Accordingly, the requirement to secure all controlled substances containing alfaxalone would not impose a significant economic burden upon DEA-registered practitioners as the infrastructure and materials for doing so are already in place. Labeling their products is routine and in the normal course of business of manufacturers. The DEA therefore assumes that the cost of compliance with 21 CFR part 1302 as a result of this final rule is nominal. Correspondingly, the DEA estimates that the cost of the labeling and packaging requirements of this final rule is nominal for the authorized manufacturer. Accordingly, compliance would not require significant additional manpower, capital investment, or recordkeeping burdens.

Because of these facts, this rule will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*), the DEA has determined and certifies pursuant to UMRA that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year * * * .'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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 (CRA). 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 for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; 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. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is 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. Amend § 1308.14 by redesignating paragraphs (c)(1) through (c)(53) as paragraphs (c)(2) through (c)(54) and adding new paragraph (c)(1) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(1) Alfaxalone—(2731)

* * * * *

Dated: February 21, 2014.

Michele M. Leonhart,

Administrator.

[FR Doc. 2014–04332 Filed 2–26–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Parts 50 and 59

[Docket No. 145; AG Order No. 3420–2014]

Policy Regarding Obtaining Information From, or Records of, Members of the News Media; and Regarding Questioning, Arresting, or Charging Members of the News Media

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Final rule.

SUMMARY: This rule amends the policy of the Department of Justice regarding the use of subpoenas, certain court orders, and search warrants, to obtain information from, or records of, members of the news media. The rule also amends the Department's policy regarding questioning, arresting, or charging members of the news media.

DATES: This rule is effective on February 27, 2014.

FOR FURTHER INFORMATION CONTACT: Monique Roth, Director, Office of Enforcement Operations, Criminal Division, (202) 514–6809.

SUPPLEMENTARY INFORMATION:

Discussion

In May of 2013, the Department initiated a comprehensive evaluation of its practices and policies regarding the use of subpoenas, court orders, and search warrants to obtain information from, or records of, members of the news media. As part of this process, the Department convened a series of meetings to solicit input from a wide range of news media stakeholders, First Amendment academics and advocates, and Members of Congress. Based on this review, the Department issued a report on July 12, 2013, announcing changes to the Department's policies.

This final rule revises the existing provisions in the Department's regulations at 28 CFR 50.10. The revisions are intended to ensure that, in determining whether to seek information from, or records of, members of the news media, the Department strikes the proper balance among several vital interests: (1) Protecting national security, (2) ensuring public safety, (3) promoting effective law enforcement and the fair administration of justice, and (4) safeguarding the essential role of the free press in fostering government accountability and an open society.

The revisions also ensure more robust oversight by senior Department officials; centralize the internal review and evaluation process; set out specific standards for the use and handling of information obtained from, or records of, members of the news media; and extend the policies to cover the use of subpoenas, court orders issued pursuant to 18 U.S.C. 2703(d) and 3123, and search warrants.

The changes to the policy also strengthen the presumption that Department attorneys will negotiate with, and provide advance notice to, affected members of the news media when investigators seek to obtain from third parties communications records or