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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 120

[Docket No.: FAA-2012-0688; Amdt. No. 120-1]

RIN 2120-AK01

Combined Drug and Alcohol Testing Programs

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rulemaking allows air carrier operators and commuter or on-demand operators that also conduct commercial air tour operations to combine the drug and alcohol testing required for each operation into one testing program. The current rule requires those operators to conduct separate testing programs for their commercial air tour operations. This results in an unnecessary duplication of effort. The intended effect of this rulemaking is to decrease operating costs by eliminating the requirement for duplicate programs while maintaining the level of safety intended by existing rules. This final rule also clarifies existing instructions within the rule, corrects a typographical error, and removes language describing a practice that has been discontinued.

DATES: Effective September 13, 2013. Any currently held exemptions allowing part 121 or part 135 operators to combine their drug and alcohol testing programs with the testing programs for their commercial air tour operations will expire on the effective date of this rule.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see “How To Obtain Additional Information” in the

SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Rafael Ramos, Office of Aerospace Medicine, Drug Abatement Division, AAM-800, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-8442; facsimile (202) 267-5200; email: drugabatement@faa.gov.

For legal questions concerning this action, contact Neal O’Hara, Attorney, Office of the Chief Counsel—International Law, Legislation, and Regulations Division, AGC-200, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-5348; email: neal.o'hara@faa.gov.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency’s authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Chapter 451, Section 45102—Alcohol and Controlled Substances Testing. Under that section, the FAA is charged with prescribing regulations for operators to establish and to conduct pre-employment, reasonable suspicion, random, and post-accident drug and alcohol testing. Parts of this rule, for example those sections dealing with contract air traffic controllers, were promulgated under the FAA’s general rulemaking authority in 49 U.S.C. 44701(a)(5). This regulation is within the scope of that authority.

I. Overview of Final Rule

Some part 121 air carriers and part 135 commuter and on-demand operators also conduct commercial air tours. Part 121 and part 135 each contain requirements for drug and alcohol testing. Until 2007, an operator’s drug and alcohol testing program covered its commercial air tour operations.

In 2007, the National Air Tour Safety Standards rule (72 FR 6884, February 13, 2007) established a separate subpart in part 91 to govern commercial air tour operators. That rule required drug and

alcohol testing for commercial air tour operations that was separate from, and in addition to, the testing required by part 121 and part 135. This final rule gives part 121 and part 135 operators with commercial air tour operations the option of administering one drug and alcohol testing program that will cover both operations. The intent of this action is to lessen the administrative burden on such operators.

This rule also includes four other actions—

1. It makes clear that operators obtaining a Letter of Authorization from the local Flight Standards District Office (FSDO) to conduct commercial air tour operations are considered to have registered their drug and alcohol testing program by submitting certain information to the FSDO.

2. It corrects the omission of a reference reiterating that on-duty use of alcohol is grounds for permanent disqualification from service. That reference was inadvertently left out of the May 14, 2009, final rule titled “Drug and Alcohol Testing Program” (74 FR 22653).

3. It reorganizes existing rule text to alleviate any confusion about the requirement that training of supervisors, as well as training of employees, must be documented as part of each employer’s employee assistance program.

4. It makes clear that the Agency’s practice of approving the employer’s drug and alcohol testing program has been discontinued.

II. Background

As noted above, in May 2009, the FAA published the Drug and Alcohol Testing Program rule. That rule moved the drug and alcohol testing regulations into a new part 120.

Part 120 of Title 14 of the Code of Federal Regulations (CFR) requires the establishment of a drug and alcohol testing program designed to prevent accidents and injuries that result from the use of prohibited drugs and the misuse of alcohol. Specifically, the rule requires three groups of operators to implement a drug and alcohol testing program:

- Part 119 certificate holders authorized to conduct part 121 operations.
- Part 119 certificate holders authorized to conduct part 135 operations.

• Commercial air tour operators as defined in § 91.147.

These requirements are meant to ensure that any person who performs safety-sensitive functions for these operators, either directly or by contract (including subcontractor at any tier), is subject to drug and alcohol testing.

Under the current rules, operators who are conducting a part 121 or part 135 operation and commercial air tour operations must administer separate drug and alcohol testing programs. Numerous operators have petitioned the FAA for an exemption from the requirement to maintain two separate drug and alcohol testing programs because having two programs often requires testing the same employees twice. This duplication adds administrative and financial burdens for the operator but it does not increase safety.

Since 2008, the FAA has granted approximately 135 exemptions allowing operators to implement a single testing program. Given the large number of exemptions that the Agency has granted, and the need to renew them every two years, the FAA believes it is appropriate to simply amend the existing rule. This approach relieves operators from seeking an operator-specific exemption. In granting these exemptions, the FAA has recognized that, in most cases, the same employees and equipment are used interchangeably between the part 121 or part 135 operation and its commercial air tour operation. Therefore, the FAA has found that when a part 119 certificate holder operates both a part 121 or a part 135 operation and a § 91.147 commercial air tour operation, combining the two testing programs maintains a level of safety equivalent to that provided by the current regulations. Under one testing program, employees are still subject to drug and alcohol testing in accordance with part 120. Any existing exemptions for combined testing programs held by part 121 or part 135 operators that also conduct § 91.147 operations will expire on the effective date of this rule. Those certificate holders with current exemptions need not take any action to comply with the requirements outlined in this rule.

III. Discussion of Public Comments

On July 2, 2012, the FAA published a Notice of Proposed Rulemaking (NPRM) (77 FR 39194), entitled “Combined Drug and Alcohol Testing Programs.” The comment period for the NPRM closed on August 31, 2012. The FAA received four comments to the NPRM. The National Air Transportation Association expressed its support for

the proposed rule, noting that the rule would reduce costs and ease administrative burdens without compromising safety.

One individual suggested that combining the two testing programs should be a requirement rather than an option. The FAA believes that most operators will take advantage of the option to reduce the amount of work and cost involved in administering duplicate testing. Regardless of how many operators take advantage of this option, however, it would not be appropriate to require it. While combining programs may have financial and administrative benefits, it has no safety benefit.

The Drug and Alcohol Testing Industry Association (DATIA) commented in support of this rule and requested that the FAA address how operators can make the transition from two programs to one and how Management Information System (MIS) information should be reported after combining the programs. The FAA will post instructional information in a separate document on its Drug Abatement Web site (<http://www.faa.gov/go/drugabatement>) for part 119 certificate holders operating part 121 or part 135 operations and § 91.147 operations to describe what must be done when first seeking to combine programs. The first step is for the part 121 or part 135 operator to advise the Principal Operations Inspector (POI) that one program will be implemented for both the part 121 or part 135 operation and the § 91.147 operation. The POI will annotate the § 91.147 operator's records (Letter of Authorization (LOA)) with an “A3” and the part 121 or part 135 certificate number to indicate that the programs are combined. The operator must then give the same notification to the FAA's Drug Abatement Division. Once a single testing program is established, the part 121 or part 135 operation must submit a single MIS report. The FAA wishes to emphasize that an operator currently holding an exemption to conduct one combined drug and alcohol testing program is not required to take any action to continue administering its combined testing program.

Another comment was received from the Aircraft Owners and Pilots Association (AOPA) regarding the proposal that, under a combined testing program, the FAA would take enforcement action for noncompliance against the part 121 or part 135 operation, even if the pilot whose testing is in question is only used for § 91.147 commercial air tour operations. The AOPA maintains that the FAA

should be able to discern which operation was responsible for the infraction and adjust the enforcement action accordingly. The FAA, however, assesses penalties against the employer, not the type of operation. Under this rule, once the two programs have been combined, they become one program. So, for example, when a part 121 operator fails to give a pre-employment drug test to a pilot who conducts part 121 and air tour flights, the part 121 operator has responsibility for the error. Therefore, any civil penalties for regulatory violations are assessed at the part 121 or part 135 operator level. This is consistent with existing exemptions allowing part 119 certificate holders to combine their part 121 or part 135 operation's testing program with their § 91.147 commercial air tour operation's testing program.

Additionally, AOPA commented that the proposed language for clarifying the consequence of on-duty alcohol use was still not completely clear and suggested alternate language. The FAA agrees with AOPA's comment and has adopted its suggested language for § 120.221(b).

IV. Discussion of Other Provisions in the Final Rule

The NPRM proposed provisions identical to those codified here with the exception that the wording of a few sections have been revised to make their meaning clearer. The headings of §§ 120.117(e) and 120.225(e) have been changed along with the regulatory language to clarify that the procedure for registering a drug and alcohol testing program for a § 91.147 commercial air tour operator is similar to the procedure used to obtain a drug and alcohol testing program operations specification for a part 121 or part 135 operator. Specifically, the revised rule requires the commercial air tour operator to submit certain information to the local FSDO instead of the Drug Abatement Division. In addition, paragraph (f) of both §§ 120.117 and 120.225 have been changed slightly to clarify that the paragraphs apply to employers who are not certificated air carriers or commercial air tour operators. Also, the wording of § 120.221 has been revised. The meaning and intent of § 120.221 have not changed from what was originally proposed.

This rule amends §§ 120.117 and 120.225 to give a part 121 or part 135 operator the option of including its commercial air tour operation employees under § 91.147 in a combined drug and alcohol testing program.

This rule also clarifies the requirement for registering a drug and

alcohol program for a § 91.147 commercial air tour operator by aligning that requirement with the requirements for obtaining a drug and alcohol program operations specification for a part 121 or part 135 operator. Currently, § 91.147 specifies that operators intending to begin commercial air tour operations must obtain a Letter of Authorization which includes an "Antidrug and Alcohol Misuse Prevention Program registration." The current §§ 120.117 and 120.225, which contain the drug and alcohol testing requirements that apply to commercial air tour operations, refer to a need for operators intending to begin commercial air tours to "register with the FAA." This rule changes §§ 120.117(e) and 120.225(e) to clarify that operators obtaining a Letter of Authorization from their local FSDO are considered to have registered their drug and alcohol testing program by submitting certain information to the local FSDO. In addition, the language of §§ 120.117(f) and 120.225(f) was changed slightly to indicate that it applies to contractors and repair stations, but not to certificated air carriers or commercial air tour operators. Also, the FAA has removed language in § 120.117(e) and (f) and § 120.225(e) and (f) that referred to submitting information to the FSDO in duplicate. The FAA does not need the information to be submitted in duplicate.

Other errors in the Agency's 2009 Drug and Alcohol Testing Program final rule were also brought to the FAA's attention. In § 120.221(b), references to §§ 120.19(c) and 120.37(c) were inadvertently omitted. The omitted references point the reader to existing §§ 120.19(c) and 120.37(c), which indicate that one occurrence of on-duty alcohol use carries the consequence of permanent disqualification from service. The FAA has corrected that error and has reorganized that paragraph for clarity.

Additionally, when the FAA combined part 121 appendices I and J to form part 120, the FAA renumbered the requirements. This reorganization created some confusion in § 120.115, which contains the requirement that employers must include documentation of the training given to both supervisors and employees in their employee assistance programs. When moving these requirements from appendix I to the subpart in part 120, not only did the FAA need to assign new section numbers to the requirements but the FAA also needed to list the details of those requirements under separate line numbers. Requirements that had been previously stated in one paragraph were

now broken into separate lines. For § 120.115, the requirements were ultimately numbered in such a way that it appeared that employers needed only to retain employee training records. The FAA is reordering the wording to make it clear that supervisory training must be documented as well. It was never the FAA's intention to change this requirement.

Finally, in 2004, the FAA discontinued the practice of approving drug and alcohol testing programs. That language was never removed from the Code of Federal Regulations. This rule amends § 120.115 to remove "submitted to the FAA for approval."

V. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96-39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

(1) The final rule is voluntary. The final rule does not impose new regulatory requirements or additional costs.

(2) The final rule is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866;

(3) The final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act;

(4) The final rule will not have a significant effect on international trade; and

(5) The final rule will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector, by exceeding the monetary threshold identified.

(6) No comments were received on the economic portions of the NPRM during the public comment period.

These analyses are summarized below.

Currently, part 121 operators or part 135 operators who also conduct air tour operations must have separate drug and alcohol testing programs for the air tour operations and their other (part 121 or part 135) operations. The intended effect of this rulemaking is to decrease this duplicative drug and alcohol testing by eliminating the requirement for two testing programs while maintaining the level of safety required by the current drug and alcohol testing regulations. This may reduce operators' costs by allowing them to eliminate one testing program and its associated costs. This final rule will also reduce the FAA's costs by reducing the number of drug and alcohol testing programs that the FAA will have to inspect.

In addition, this rulemaking allows the agency to clarify that air tour operators obtaining a Letter of Authorization from the local FSDO to conduct air tour operations are considered to have registered their drug and alcohol testing program by submitting certain information to the FSDO. This may reduce costs to the operators and the FAA by reducing the amount of time spent attempting to clarify requirements.

Based on the above analyses, this final rule is considered to be a cost-relieving rule. For this reason, and because the FAA made a similar determination for the proposed rule and received no comment on this point, the FAA believes that the final rule will reduce costs with no loss of benefits. Thus this final rule is cost beneficial.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective

of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation." To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the Act.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

Size Standards

Size standards for small entities are published by the Small Business Administration (SBA) on their Web site at <http://www.sba.gov/size>. The size standards used herein are from "SBA U.S. Small Business Administration, Table of Small Business Size Standards, Matched to North American Industry Classification System Codes." The Table is effective November 5, 2010, and uses the 2007 NAICS codes. Scheduled Passenger Air Transportation is listed in Sector 48–49—Transportation and Warehousing; Subsector 481—Air Transportation; NAICS Code 48111. Non-Scheduled Chartered Passenger Air Transportation is listed under the same Sector and Subsector with NAICS code 481211. In both cases the small entity size standard is 1,500 employees.

It is estimated that most of the air carriers involved in this type of activity are small entities. Therefore, the final rule affects a large number of small entities.

However, the final rule imposes no costs and may result in a cost reduction for an entity that should choose to use the final rule. No comments were received on the Regulatory Flexibility Section of the NPRM. Therefore, the FAA Administrator certifies that this final rule will not have a significant economic impact on a substantial

number of small part 119 certificate holders that conduct part 121 operations or part 135 operations and commercial air tour operations under § 91.147.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. No comments were received on this section in the NPRM during the public comment period. The FAA has assessed the potential effect of this final rule and has determined that it will have little or no effect on international trade.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." The FAA currently uses an inflation-adjusted value of \$143.1 million in lieu of \$100 million. No comments on this section in the NPRM were received during the public comment period. This final rule does not contain such a mandate; therefore, the requirements of Title II do not apply.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new information collection associated with allowing operators to combine drug and alcohol testing programs.

International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these regulations.

Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, (77 FR 26413, May 4, 2012) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312d and involves no extraordinary circumstances.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The

agency has determined that it is not a “significant energy action” under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

VII. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet—

1. Search the Federal eRulemaking Portal at <http://www.regulations.gov>;
2. Visit the FAA’s Regulations and Policies Web page at http://www.faa.gov/regulations_policies/ or
3. Access the Government Printing Office’s Federal Digital System Web page at <http://www.gpo.gov/fdsys/>.

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680.

B. Comments Submitted to the Docket

Comments received may be viewed by going to <http://www.regulations.gov> and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA’s dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects in 14 CFR Part 120

Alcoholism, Air carriers, Air traffic control, Airmen, Alcohol abuse, Alcohol testing, Aviation safety, Charter flights, Commercial air tour operators, Contract air traffic controllers, Drug abuse, Drug testing, Operators, Reporting and recordkeeping requirements, Safety, Safety-sensitive, Transportation.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 120—DRUG AND ALCOHOL TESTING PROGRAM

- 1. The authority citation for part 120 is revised to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101-40103, 40113, 40120, 41706, 41721, 44106,

44701, 44702, 44703, 44709, 44710, 44711, 45101-45105, 46105, 46306.

- 2. Amend § 120.115 as follows:
 - a. Redesignate paragraphs (c)(1)(iii) and (c)(5) as paragraphs (c)(5) and (c)(6) respectively.
 - b. Revise newly redesignated paragraphs (c)(5) and (c)(6).

The revisions read as follows:

§ 120.115 Employee Assistance Program (EAP).

* * * * *

- (c) * * *
 - (5) Documentation of all training given to employees and supervisory personnel must be included in the training program.
 - (6) The employer shall identify the employee and supervisor EAP training in the employer’s drug testing program.

- 3. Amend § 120.117 as follows:
 - a. Revise paragraphs (a) and (b);
 - b. Redesignate paragraph (e) as paragraph (f);
 - c. Add new paragraph (e);
 - d. Revise newly redesignated paragraph (f).

The additions and revisions read as follows:

§ 120.117 Implementing a drug testing program.

(a) Each company must meet the requirements of this subpart. Use the following chart to determine whether your company must obtain an Antidrug and Alcohol Misuse Prevention Program Operations Specification, Letter of Authorization, or Drug and Alcohol Testing Program Registration from the FAA:

If you are . . .	You must . . .
(1) A part 119 certificate holder with authority to operate under parts 121 or 135.	Obtain an Antidrug and Alcohol Misuse Prevention Program Operations Specification by contacting your FAA Principal Operations Inspector.
(2) An operator as defined in §91.147 of this chapter	Obtain a Letter of Authorization by contacting the Flight Standards District Office nearest to your principal place of business.
(3) A part 119 certificate holder with authority to operate under parts 121 or 135 and an operator as defined in §91.147 of this chapter.	Complete the requirements in paragraphs 1 and 2 of this chart and advise the Flight Standards District Office and the Drug Abatement Division that the §91.147 operation will be included under the part 119 testing program. Contact the Drug Abatement Division at FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591.
(4) An air traffic control facility not operated by the FAA or by or under contract to the U.S. Military.	Register with the FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591.
(5) A part 145 certificate holder who has your own drug testing program.	Obtain an Antidrug and Alcohol Misuse Prevention Program Operations Specification by contacting your Principal Maintenance Inspector or register with the FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591, if you opt to conduct your own drug testing program.
(6) A contractor who has your own drug testing program	Register with the FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591, if you opt to conduct your own drug testing program.

(b) Use the following chart for implementing a drug testing program if you are applying for a part 119 certificate with authority to operate under parts 121 or 135 of this chapter, if you intend to begin operations as defined in § 91.147 of this chapter, or if

you intend to begin air traffic control operations (not operated by the FAA or by or under contract to the U.S. Military). Use it to determine whether you need to have an Antidrug and Alcohol Misuse Prevention Program Operations Specification, Letter of

Authorization, or Drug and Alcohol Testing Program Registration from the FAA. Your employees who perform safety-sensitive functions must be tested in accordance with this subpart. The chart follows:

If you . . .	You must . . .
(1) Apply for a part 119 certificate with authority to operate under parts 121 or 135.	(i) Have an Antidrug and Alcohol Misuse Prevention Program Operations Specification, (ii) Implement an FAA drug testing program no later than the date you start operations, and (iii) Meet the requirements of this subpart.
(2) Intend to begin operations as defined in § 91.147 of this chapter	(i) Have a Letter of Authorization, (ii) Implement an FAA drug testing program no later than the date you start operations, and (iii) Meet the requirements of this subpart.
(3) Apply for a part 119 certificate with authority to operate under parts 121 or 135 and intend to begin operations as defined in § 91.147 of this chapter.	(i) Have an Antidrug and Alcohol Misuse Prevention Program Operations Specification and a Letter of Authorization, (ii) Implement your combined FAA drug testing program no later than the date you start operations, and (iii) Meet the requirements of this subpart.
(4) Intend to begin air traffic control operations (at an air traffic control facility not operated by the FAA or by or under contract to the U.S. military).	(i) Register with the FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591, prior to starting operations, (ii) Implement an FAA drug testing program no later than the date you start operations, and (iii) Meet the requirements of this subpart.

* * * * *

(e) Register your Drug and Alcohol Testing Program by obtaining a Letter of Authorization from the FAA in accordance with § 91.147. (1) A drug and alcohol testing program is considered registered when the following information is submitted to the Flight Standards District Office nearest your principal place of business:

- (i) Company name.
- (ii) Telephone number.
- (iii) Address where your drug and alcohol testing program records are kept.
- (iv) Type of safety-sensitive functions you or your employees perform (such as flight instruction duties, aircraft dispatcher duties, maintenance or preventive maintenance duties, ground security coordinator duties, aviation screening duties, air traffic control duties).
- (v) Whether you have 50 or more covered employees, or 49 or fewer covered employees.
- (vi) A signed statement indicating that your company will comply with this part and 49 CFR part 40.

(2) This Letter of Authorization will satisfy the requirements for both your drug testing program under this subpart and your alcohol testing program under subpart F of this part.

(3) Update the Letter of Authorization information as changes occur. Send the updates to the Flight Standards District

Office nearest your principal place of business.

(4) If you are a part 119 certificate holder with authority to operate under parts 121 or 135 and intend to begin operations as defined in § 91.147 of this chapter, you must also advise the Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591.

(f) Obtaining a Drug and Alcohol Testing Program Registration from the FAA. (1) Except as provided in paragraphs (d) and (e) of this section, to obtain a Drug and Alcohol Testing Program Registration from the FAA, you must submit the following information to the Office of Aerospace Medicine, Drug Abatement Division:

- (i) Company name.
- (ii) Telephone number.
- (iii) Address where your drug and alcohol testing program records are kept.
- (iv) Type of safety-sensitive functions you or your employees perform (such as flight instruction duties, aircraft dispatcher duties, maintenance or preventive maintenance duties, ground security coordinator duties, aviation screening duties, air traffic control duties).
- (v) Whether you have 50 or more covered employees, or 49 or fewer covered employees.
- (vi) A signed statement indicating that: your company will comply with

this part and 49 CFR part 40; and you intend to provide safety-sensitive functions by contract (including subcontract at any tier) to a part 119 certificate holder with authority to operate under part 121 or part 135 of this chapter, an operator as defined in § 91.147 of this chapter, or an air traffic control facility not operated by the FAA or by or under contract to the U.S. military.

(2) Send this information to the Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591.

(3) This Drug and Alcohol Testing Program Registration will satisfy the registration requirements for both your drug testing program under this subpart and your alcohol testing program under subpart F of this part.

(4) Update the registration information as changes occur. Send the updates to the address specified in paragraph (f)(2) of this section.

■ 4. Amend § 120.221 by revising paragraph (b) to read as follows:

§ 120.221 Consequences for employees engaging in alcohol-related conduct.

* * * * *

(b) Permanent disqualification from service. (1) An employee who violates §§ 120.19(c) or 120.37(c) is permanently precluded from performing for an employer the safety-sensitive duties the

employee performed before such violation.
 (2) An employee who engages in alcohol use that violates another alcohol misuse provision of §§ 120.19 or 120.37, and who had previously engaged in alcohol use that violated the provisions of §§ 120.19 or 120.37 after becoming subject to such prohibitions, is permanently precluded from performing for an employer the safety-sensitive

duties the employee performed before such violation.
 * * * * *
 ■ 5. Amend § 120.225 as follows:
 ■ a. Revise paragraphs (a) and (b);
 ■ b. Redesignate paragraph (e) as paragraph (f);
 ■ c. Add new paragraph (e);
 ■ d. Revise newly redesignated paragraph (f).
 The additions and revisions read as follows:

§ 120.225 Implementing an alcohol testing program.
 (a) Each company must meet the requirements of this subpart. Use the following chart to determine whether your company must obtain an Antidrug and Alcohol Misuse Prevention Program Operations Specification, Letter of Authorization, or Drug and Alcohol Testing Program Registration from the FAA:

If you are . . .	You must . . .
(1) A part 119 certificate holder with authority to operate under part 121 or 135.	Obtain an Antidrug and Alcohol Misuse Prevention Program Operations Specification by contacting your FAA Principal Operations Inspector.
(2) An operator as defined in §91.147 of this chapter	Obtain a Letter of Authorization by contacting the Flight Standards District Office nearest to your principal place of business.
(3) A part 119 certificate holder with authority to operate under part 121 or part 135 and an operator as defined in §91.147 of this chapter.	Complete the requirements in paragraphs 1 and 2 of this chart and advise the Flight Standards District Office and Drug Abatement Division that the §91.147 operation will be included under the part 119 testing program. Contact Drug Abatement Division at FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591.
(4) An air traffic control facility not operated by the FAA or by or under contract to the U.S. Military.	Register with the FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591.
(5) A part 145 certificate holder who has your own alcohol testing program.	Obtain an Antidrug and Alcohol Misuse Prevention Program Operations Specification by contacting your Principal Maintenance Inspector or register with the FAA Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591, if you opt to conduct your own alcohol testing program.
(6) A contractor who has your own alcohol testing program	Register with the FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591, if you opt to conduct your own alcohol testing program.

(b) Use the following chart for implementing an alcohol testing program if you are applying for a part 119 certificate with authority to operate under part 121 or part 135 of this chapter, if you intend to begin operations as defined in § 91.147 of this

chapter, or if you intend to begin air traffic control operations (not operated by the FAA or by or under contract to the U.S. Military). Use it to determine whether you need to have an Antidrug and Alcohol Misuse Prevention Program Operations Specification, Letter of

Authorization, or Drug and Alcohol Testing Program Registration from the FAA. Your employees who perform safety-sensitive duties must be tested in accordance with this subpart. The chart follows:

If you . . .	You must . . .
(1) Apply for a part 119 certificate with authority to operate under parts 121 or 135.	(i) Have an Antidrug and Alcohol Misuse Prevention Program Operations Specification, (ii) Implement an FAA alcohol testing program no later than the date you start operations, and (iii) Meet the requirements of this subpart.
(2) Intend to begin operations as defined in §91.147 of this chapter	(i) Have a Letter of Authorization, (ii) Implement an FAA alcohol testing program no later than the date you start operations, and (iii) Meet the requirements of this subpart.
(3) Apply for a part 119 certificate with authority to operate under parts 121 or 135 and intend to begin operations as defined in §91.147 of this chapter.	(i) Have an Antidrug and Alcohol Misuse Prevention Program Operations Specification and a Letter of Authorization, (ii) Implement your combined FAA alcohol testing program no later than the date you start operations, and (iii) Meet the requirements of this subpart.
(4) Intend to begin air traffic control operations (at an air traffic control facility not operated by the FAA or by or under contract to the U.S. military).	(i) Register with the FAA, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591, prior to starting operations, (ii) Implement an FAA alcohol testing program no later than the date you start operations, and (iii) Meet the requirements of this subpart.

* * * * *

(e) Register your Drug and Alcohol Testing Program by obtaining a Letter of Authorization from the FAA in accordance with § 91.147. (1) A drug

and alcohol testing program is considered registered when the following information is submitted to the Flight Standards District Office nearest your principal place of business:

- (i) Company name.
- (ii) Telephone number.
- (iii) Address where your drug and alcohol testing program records are kept.
- (iv) Type of safety-sensitive functions you or your employees perform (such as flight instruction duties, aircraft dispatcher duties, maintenance or preventive maintenance duties, ground security coordinator duties, aviation screening duties, air traffic control duties).
- (v) Whether you have 50 or more covered employees, or 49 or fewer covered employees.
- (vi) A signed statement indicating that your company will comply with this part and 49 CFR part 40.

(2) This Letter of Authorization will satisfy the requirements for both your drug testing program under subpart E of this part and your alcohol testing program under this subpart.

(3) Update the Letter of Authorization information as changes occur. Send the updates to the Flight Standards District Office nearest your principal place of business.

(4) If you are a part 119 certificate holder with authority to operate under part 121 or part 135 and intend to begin operations as defined in § 91.147 of this chapter, you must also advise the Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591.

(f) *Obtaining a Drug and Alcohol Testing Program Registration from the FAA.* (1) Except as provided in paragraphs (d) and (e) of this section, to obtain a Drug and Alcohol Testing Program Registration from the FAA you must submit the following information to the Office of Aerospace Medicine, Drug Abatement Division:

- (i) Company name.
- (ii) Telephone number.
- (iii) Address where your drug and alcohol testing program records are kept.
- (iv) Type of safety-sensitive functions you or your employees perform (such as

flight instruction duties, aircraft dispatcher duties, maintenance or preventive maintenance duties, ground security coordinator duties, aviation screening duties, air traffic control duties).

(v) Whether you have 50 or more covered employees, or 49 or fewer covered employees.

(vi) A signed statement indicating that: your company will comply with this part and 49 CFR part 40; and you intend to provide safety-sensitive functions by contract (including subcontract at any tier) to a part 119 certificate holder with authority to operate under part 121 or part 135 of this chapter, an operator as defined in § 91.147 of this chapter, or an air traffic control facility not operated by the FAA or by or under contract to the U.S. military.

(2) Send this information to the Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division (AAM-800), 800 Independence Avenue SW., Washington, DC 20591.

(3) This Drug and Alcohol Testing Program Registration will satisfy the registration requirements for both your drug testing program under subpart E of this part and your alcohol testing program under this subpart.

(4) Update the registration information as changes occur. Send the updates to the address specified in paragraph (f)(2) of this section.

Issued under authority provided by 49 U.S.C. 106(f) and 45102 in Washington, DC, on July 1, 2013.

Michael P. Huerta,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA-2013-N-0002]

Oral Dosage Form New Animal Drugs; Nicarbazin; Oclacitinib; Zilpaterol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during May 2013. FDA is also informing the public of the availability of summaries the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective July 15, 2013.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, ghaibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during May 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/OfficeofFoods/CVMFOIAElectronicReadingRoom/default.htm>.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING MAY 2013

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
141-279	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	NICARB 25% (nicarbazin) and BMD (bacitracin meth- ylene disalicylate) Type A medicated articles.	Supplement revising nicarbazin dosage to a range consistent with dos- age approved for use in combination feeds.	558.366	No	CE ¹