

Dated: March 6, 2014.

Marianne O. Markowitz,
Acting Administrator.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 120

[Docket No.: FAA-2012-1058; Notice No. 14-02]

RIN 2120-AK09

Drug and Alcohol Testing of Certain Maintenance Provider Employees Located Outside of the United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: The FAA is considering amending its drug and alcohol testing regulations to require drug and alcohol testing of certain maintenance personnel outside the United States. Specifically, the FAA is considering requiring certain air carriers to ensure that all employees of certificated repair stations, and certain other maintenance organizations that are located outside the United States, who perform safety-sensitive maintenance functions on aircraft operated by that air carrier are subject to a drug and alcohol testing program that has been determined acceptable by the FAA Administrator and is consistent with the applicable laws of the country in which the repair station is located. Safety-sensitive maintenance functions include aircraft maintenance and preventive maintenance duties. This action is necessary to address a statutory mandate. The FAA has determined that it needs additional information to develop a proposed rule and assess its likely economic impact. This notice invites comments on a variety of issues related to proposing drug and alcohol testing requirements for the relevant employees of covered maintenance providers.

DATES: Send comments on or before May 16, 2014.

ADDRESSES: Send comments identified by docket number FAA-2012-1058 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of

Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at (202) 493-2251.

Privacy: In accordance with 5 USC 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy. <http://DocketsInfo.dot.gov>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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, Regulations Division, AGC-240, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-5348.

For cost and benefit questions concerning this action, contact Nicole Nance, Office of Aviation Policy and Plans, APO-300, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-3311.

SUPPLEMENTARY INFORMATION:

Comments Invited

See the "Additional Information" section for information on how to comment on this ANPRM and how the FAA will handle comments received. The "Additional Information" section also contains related information about the docket, privacy, and the handling of

proprietary or confidential business information. In addition, there is information on obtaining copies of related rulemaking documents.

Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in title 49 of the United States Code (U.S.C.). 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. In carrying out part A (Air Commerce and Safety) of subtitle VII, the Administrator is directed to act consistently with obligations of the United States Government under an international agreement and to consider applicable laws and requirements of a foreign country. See 49 U.S.C. 40105(b)(1)-(2). Additionally, section 308(d)(2) of the FAA Modernization and Reform Act of 2012 (the Act), 49 U.S.C. 44733 requires that:

Not later than 1 year after the date of enactment of this section, the [FAA] Administrator shall promulgate a proposed rule requiring that all part 145 repair station employees responsible for safety-sensitive maintenance functions on part 121 air carrier aircraft are subject to an alcohol and controlled substances testing program determined acceptable by the Administrator and consistent with the applicable laws of the country in which the repair station is located.¹

In 49 U.S.C. 44733(d)(2) Congress did not address employees of maintenance providers located outside the United States that are not certificated by the FAA. However, authorized persons performing safety-sensitive maintenance functions on aircraft operated by part 121 air carriers in accordance with 14 CFR 43.17 are substantially similar to those employees of part 145 repair stations located outside the United States for whom the FAA has been directed to propose drug and alcohol testing. Because of their substantial similarity, under the authority of 49 U.S.C. 44701(a)(5), which requires the Administrator to promote the safe flight of civil aircraft in air commerce by prescribing regulations and minimum standards for practices, methods, and procedures that the Administrator finds necessary for safety in air commerce and national security, we request comment on the application of these requirements to this group/category of authorized persons.

¹ Except when quoting the text of section 308 of the Act, the FAA uses the term "drug" rather than "controlled substance" in this ANPRM, because an illegal substance in the United States may be legal to use in the country in which a covered maintenance provider is located.

I. Overview of Advance Notice of Proposed Rulemaking (ANPRM)

The Act requires the FAA to propose alcohol and drug testing requirements for employees of part 145 repair stations located outside the United States who perform safety-sensitive maintenance functions on aircraft operated by part 121 air carriers, as the FAA currently does not require drug or alcohol testing for such personnel. Currently, as required under 14 CFR part 120, employees performing aircraft maintenance and preventive maintenance duties on part 121, 135 or 91.147 certificated aircraft within the U.S. are required to be subject to drug and alcohol testing. The FAA believes Congress intended that preventive maintenance is a safety-sensitive maintenance function as currently described under 14 CFR part 120, therefore safety-sensitive maintenance functions include both aircraft maintenance and preventive maintenance duties.²

While Congress did not address maintenance providers that are not certificated by the FAA in 49 U.S.C. 44733(d)(2), authorized persons performing safety-sensitive maintenance functions on aircraft operated by part 121 air carriers in accordance with 14 CFR 43.17, are substantially similar to the employees of part 145 repair stations in other countries for whom the FAA must propose drug and alcohol testing. Therefore, the FAA is also considering whether to require each part 121 air carrier to ensure that authorized persons performing safety-sensitive maintenance functions on aircraft operated by that part 121 air carrier in accordance with 14 CFR 43.17, and is not also a certificated part 145 repair station, are subject to drug and alcohol testing programs that meet the same or similar requirements as programs for their counterparts at part 145 repair stations located outside the United States.

Currently, there are approximately 120 part 145 repair stations located outside the United States whose employees perform safety-sensitive maintenance functions on aircraft operated by part 121 air carriers. There are also organizations in one other country outside the United States that are not part 145 repair stations, but whose employees perform safety-

sensitive maintenance functions on aircraft operated by part 121 air carriers in accordance with 14 CFR 43.17.

II. Background

A. Statement of the Issue

The FAA's drug and alcohol testing regulations, contained in 14 CFR part 120, do not extend to companies or individuals who perform safety-sensitive functions, including, but not limited to, aircraft maintenance and preventive maintenance, outside of the United States. They currently apply to all air carriers and operators authorized to conduct operations under part 121 or part 135; all air traffic control facilities not operated by the FAA or by or under contract to the U.S. military; all air tour operators as defined in 14 CFR 91.147; and all part 145 certificate holders and contractors who employ individuals who perform, either directly or by contract, including subcontract at any tier, any of the following safety-sensitive functions: Flight crewmember duties, flight attendant duties, flight instruction duties, aircraft dispatcher duties, aircraft maintenance and preventive maintenance duties, ground security coordinator duties, aviation screening duties, air traffic control duties. Additionally, the regulations do not permit any part of the testing process, including specimen collection, to be conducted outside the United States. As described above, the Act requires that the FAA propose extending drug and alcohol testing to employees of part 145 repair stations located outside the United States who perform safety-sensitive maintenance functions on part 121 air carrier aircraft in a manner consistent with local laws.

B. International Civil Aviation Organization (ICAO) Standards and Recommended Practices

International Civil Aviation Organization (ICAO) standards do not presently require ICAO Member States to establish (or direct industry to establish) testing programs to deter or detect inappropriate drug and alcohol use by aviation personnel with safety-sensitive responsibilities. However, a number of ICAO standards and recommended practices address misuse of drugs and alcohol by aviation personnel and recognize the potential hazard that such misuse may pose to aviation safety. For example, the recommended practice in paragraph 1.2.7.3 of Annex 1 (Personnel Licensing) to the Convention on International Civil Aviation (the "Chicago Convention"), states that ICAO Member States ". . . should ensure, as far as practicable, that

all licen[s]e holders who engage in any kind of problematic use of substances are identified and removed from their safety-critical functions." ICAO further recommends that "[r]eturn to the safety-critical functions may be considered after successful treatment or, in cases where no treatment is necessary, after cessation of the problematic use of substances and upon determination that the person's continued performance of the function is unlikely to jeopardize safety." In addition, the standard in paragraph 2.5 of Annex 2 (Rules of the Air) to the Chicago Convention states that "[n]o person whose function is critical to the safety of aviation (safety-sensitive personnel) shall undertake that function while under the influence of any psychoactive substance, by reason of which human performance is impaired. No such person shall engage in any kind of problematic use of substances." See also paragraphs 1.2.6, 1.2.7, 6.3.2.2, 6.4.2.2, and 6.5.2.2 of Annex 1 to the Chicago Convention.

C. History

The FAA's original drug testing rule, published in 1988 (53 FR 47024), required drug testing of certain aviation personnel, including some that performed safety-sensitive functions outside the United States. However, the effective date of the rule with respect to testing outside the territory of the United States was deferred on a number of occasions to permit related negotiations with governments and international organizations to continue in an orderly and effective fashion. In 1994, the FAA published two final rules related to drug and alcohol testing. *Alcohol Misuse Prevention Program for Personnel Engaged in Specified Aviation Activities* (59 FR 7380) established the FAA's alcohol testing requirements. The alcohol testing rule was not extended to employees located outside the territory of the United States due to significant logistical issues and possible conflicts with local laws. *Anti-Drug Program for Personnel Engaged in Specified Aviation Activities* (59 FR 42922) amended certain provisions of the existing FAA drug testing rules to comply with the requirements of the Omnibus Transportation Employee Testing Act of 1991. The drug testing requirements were not extended to employees located outside of United States territory due to significant practical and legal concerns. Rather, the rule specifically stated that no employee located outside of the United States would be tested for drugs. Additionally, in 1994, the FAA published a Notice of Proposed Rulemaking (NPRM), *Antidrug Program and Alcohol Misuse*

² Alcohol and drug testing of employees of part 145 repair stations located in the United States who perform safety-sensitive maintenance functions on aircraft operated by part 121 air carriers is already required under 14 CFR part 120. The FAA does not anticipate making any changes as part of this rulemaking to its drug and alcohol testing requirements that apply to safety-sensitive personnel within the United States.

Prevention Program for Employees of Foreign Air Carriers Engaged in Specified Aviation Activities, to address requirements in the Omnibus Transportation Employee Testing Act of 1991. This NPRM required foreign air carriers operating into the U.S. to implement testing programs like those required of U.S. air carriers unless “multilateral action was taken to support an international aviation environment free of substance abuse”. However, in 2000, the FAA withdrew the NPRM stating, “For the foregoing reasons, the FAA is withdrawing the rulemaking proposed on February 15, 1994, and is leaving within the purview of each government the method chosen to respond to the ICAO initiatives. We will continue to view a multilateral response as the best approach to evolving issues in the substance abuse arena. Should the FAA subsequently determine, however, that the scope of the threat of substance abuse is not being adequately addressed by the international community, the FAA will take appropriate action, including the possible re-initiation of this rulemaking.”

D. Related Actions

Under 49 U.S.C. 44733(d)(1), Congress mandated that the Secretary of State and the Secretary of Transportation, acting jointly, request the governments of countries that are members of ICAO to establish international standards for alcohol and drug testing of persons that perform safety-sensitive maintenance functions on commercial air carrier aircraft. The FAA strongly supports the development of such international standards and believes that they would help deter and detect drug and alcohol use that could compromise aviation safety.

III. Discussion of Proposals Under Consideration

Although ICAO standards and many countries’ aviation regulations prohibit the use of drugs and alcohol by certain aviation personnel in circumstances in which such use may threaten aviation safety, many countries either do not require testing of such personnel to verify compliance or do not extend such testing to maintenance personnel. Congress, however, has now enacted legislation that requires the FAA to propose a rule requiring that all Part 145 repair station employees responsible for safety-sensitive maintenance functions on part 121 air carrier aircraft, not just those in the United States, be subject to a drug and alcohol testing program that is acceptable to the Administrator and consistent with the applicable laws of

the country in which the repair station is located.

The FAA is aware, however, that establishing drug and alcohol testing requirements for such personnel presents complex practical and legal issues and could impose potentially significant costs on industry. Therefore, the FAA is issuing this ANPRM, rather than an NPRM, to seek comments from the public, as well as interested governments, to help inform the development of a proposed rule and the analysis of its economic impact.

The FAA expects to propose to allow the testing process to take place outside the United States.³ Any part of the testing process conducted outside the United States would need to be both acceptable to the Administrator and permitted under the applicable laws and regulations of the relevant foreign country or countries. The FAA believes that it would be less expensive and logistically simpler to conduct testing for the relevant employees of covered maintenance providers in the country where the covered maintenance provider is located or possibly in a nearby country.

The FAA understands that other countries may have a wide variety of laws and regulations concerning the use of and testing for alcohol and drugs. The FAA further understands that other countries’ laws and regulations concerning other matters, such as personal privacy and employment, may affect whether and under what circumstances drug and alcohol testing may be conducted in those countries. Some countries might need to pass authorizing legislation before they could permit testing within their borders. The FAA also recognizes the diversity of policy, moral, and religious views that exist internationally regarding drug and alcohol use and testing.

The FAA seeks input from the public and interested governments to help inform the development of a proposed rule and the analysis of its economic impact. In responding to the requests for comment below, the FAA asks that commenters distinguish between responses relating to alcohol testing and those relating to drug testing, if the same comment does not apply to both.

A. Foreign Countries Laws and Regulations

To help the FAA expand its understanding of the laws and regulations of other countries that bear on drug and alcohol testing, the FAA requests the information described

below regarding countries in which covered maintenance providers are located. It would be particularly helpful to receive the requested information regarding the countries’ laws and regulations from the responsible government authorities of the relevant country, although private parties are also encouraged to provide information.

A 1. Is drug and alcohol testing of any aviation personnel required in that country, and, if so, for what categories of aviation personnel (e.g., pilots, flight attendants, maintenance personnel, flight dispatchers, others (please specify))?

A 2. Please provide an explanation of laws and regulations on other subjects, such as personal privacy or employment, which may affect the permissibility of drug and alcohol testing in the country, the circumstances under which such testing may be conducted, or the manner in which it may be conducted. Please include information on which categories of aviation personnel are subject to these requirements (e.g., pilots, flight attendants, maintenance personnel, flight dispatchers, others (please specify)). English language copies of the applicable laws and regulations would be greatly appreciated.

A 3. What types of testing are (a) permitted and (b) required under the laws and regulations of the country? Please address the following testing by type:

- a. Pre-employment testing;
- b. Random testing during employment;
- c. Periodic testing during employment;
- d. Testing based on a reasonable cause/suspicion that an employee is under the influence of alcohol or drugs while performing a safety-sensitive function or within a certain period of time before or after performing such a function;
- e. Post-accident testing;
- f. Return-to-duty and follow-up testing of individuals who have previously tested positive for alcohol or drugs;
- g. Any other drug or alcohol testing (please specify)?

A 4. Should an FAA regulation include a provision to allow regulated parties to apply for a waiver⁴ if any provision conflicts with a foreign law or regulation? Please state the rationale for

³ For example, suitable laboratory facilities for analyzing specimens would need to be available.

⁴ Based on the waiver provision in the Office of the Secretary of Transportation’s non-discrimination on the basis of disability in air travel regulations described in 14 CFR § 382.9.

why such a waiver provision should or should not be included.

B. Program Elements of Acceptable Drug and Alcohol Testing

The FAA is considering addressing the program elements listed below in establishing the criteria for determining whether a drug and alcohol testing program is acceptable to the Administrator. Questions associated with each program element are listed below.

1. *A defined set of circumstances under which testing is conducted for alcohol and the most pervasive drugs of abuse in the relevant country.* Under the FAA's current domestic drug and alcohol testing regulations for persons performing flight crewmember duties, flight attendant duties, flight instructor duties, aircraft dispatcher duties, aircraft maintenance and preventive maintenance duties, ground security coordinator duties, aviation screening duties, air traffic control duties testing is required in the following circumstances:

- Pre-employment (for drugs only);
- Randomly during employment;
- After an accident;
- If there is reasonable cause/

suspicion to believe that an individual is under the influence of alcohol or drugs while performing safety-sensitive functions or within a certain period of time before or after performing such functions;

- Return-to-duty testing and follow-up testing before and after returning an employee to duty who previously tested positive for alcohol or drugs or refused to submit to testing.

B1. For a program to be found acceptable to the Administrator, should the FAA require that testing be conducted under all of the above circumstances for which it is required in the U.S.? If not, under what circumstances should testing be required?

2. *Types of substances tested.* 49 U.S.C. 44733(d)(2) requires that the proposed rule include "alcohol and controlled substances testing". The substances that are tested in the United States include alcohol, marijuana, cocaine, opiates, phencyclidine (PCP), and amphetamines. The FAA recognizes that the drugs of concern in other countries may vary depending upon conditions in those countries. Therefore, the FAA poses the following questions:

B2a. Should an acceptable program require testing for, at a minimum, the drugs for which the FAA requires testing in the United States? If not, please provide information on which drugs should be tested for, at a

minimum, to constitute an acceptable program.

B2b. At what concentrations should a test for alcohol, drugs, or their metabolites be considered positive? Should an acceptable program identify set ceiling concentrations above which tests must be considered positive? If so, what should those levels be?

3. *A mechanism that is an effective deterrent to drug and alcohol misuse.* The FAA views random testing as an effective deterrent because there is an element of surprise. Employees subject to random testing receive little notice before they must report for testing. Other countries or industry may have developed other effective methods of deterrence and some countries may prohibit or significantly restrict the use of random testing. The FAA poses the following questions with respect to this potential program element:

B3a. Does the country allow or require random drug and/or alcohol testing? If so, please describe the process.

B3b. If the country does not allow or require random drug and/or alcohol testing, are there laws to prohibit random testing?

B3c. If random testing is not allowed in a given country, what other methods could be used to successfully deter employees from misusing drugs or alcohol while performing safety-sensitive duties or within a certain period of time before performing such duties? How would such misuse be detected?

4. *Procedures that ensure the integrity, identity, and proper analysis of the collected specimen to ensure accuracy of the test result.* In the United States, the U.S. Department of Transportation has adopted a chain-of-custody process developed by the U.S. Department of Health and Human Services (HHS) to document the handling and storage of a specimen from the time it is collected until the time it is released to the testing facility. This process, coupled with the FAA's requirement that testing programs in the United States use a laboratory certified by HHS, helps ensure the accuracy of testing results. The FAA poses the following questions with respect to this potential program element:

B4a. What testing methods, if any, in addition to those currently permitted under part 120, should be permitted in programs outside the United States?

B4b. What standards should personnel and laboratories or other facilities in foreign countries be required to meet? Please address the following matters:

- Personnel qualifications;

- Measures to prevent adulteration, substitution, or mistaken identification of specimens;

- Measures to ensure drug and alcohol testing information is only released to authorized persons;

- Measures to determine whether there is a legitimate medical explanation for a positive test result;

- Other relevant considerations (please specify).

B4c. HHS-certified laboratories are not available outside the United States; therefore, should a program be acceptable if it allows the use of other laboratories that have been certified by DOT, another regulatory authority, or international organization as meeting equivalent or more stringent international standards?

5. *A means of ensuring that an employee who returns to work [after violating the law] is no longer misusing alcohol or drugs.* If an employee who violated the drug or alcohol regulations is permitted to return to work, it is important to have a means for ensuring that the employee is no longer misusing alcohol or drugs and a means of detecting such misuse if it recurs after the employee returns to safety-sensitive duties. The return-to-duty process in the United States is described in the Department of Transportation's regulations at 49 CFR part 40, subpart O. The FAA poses the following questions with respect to this potential program element:

B5a. What are the minimum standards that employees who have violated drug and alcohol regulations should meet before they return to performing safety-sensitive maintenance functions?

B5b. If follow-up testing is not permitted, what other methods would ensure that an employee who has previously tested positive for alcohol or drugs does not misuse them again after returning to safety-sensitive duties?

C. Existing Drug and Alcohol Testing Programs in Other Countries

The FAA recognizes that existing drug and alcohol testing programs in other countries may take various forms and must comply with the applicable laws and regulations of those countries. In some countries, drug and alcohol testing programs may be established by industry in accordance with regulations promulgated by a government agency, as is the case in the United States. In others, a government agency may administer a national drug and alcohol testing program. In yet others, industry participants may have voluntarily established drug and alcohol testing programs as a good business practice or for competitive advantage in the

marketplace without being required to do so. In addition to the information provided in part B above, the FAA requests the information described below about existing drug and alcohol testing programs in other countries, whether legally mandated or voluntarily established. The FAA is interested in both nationwide information for other countries and information pertaining to the testing programs of specific companies or the members of an association:

C 1. Which drugs are most pervasively misused in the country? Please provide data to support this answer.

C 2. Are testing programs in the country:

- a. Administered by a national regulatory authority;
- b. Required to be established by industry participants under that country's laws and regulations;
- c. Voluntarily established by industry participants;
- d. Other (please specify)?

C 3. Please describe the process that is followed after an employee's drug test is confirmed positive or alcohol concentration is confirmed to be above the permitted limit, including at what point an individual would be removed from safety-sensitive duty.

C 4. If the country allows drug or alcohol testing, what protections does the country's legal system provide for the employee?

C 5. What are the potential consequences in that country, including, but not limited to, enforcement action by the relevant government authority, when an individual who performs safety-sensitive aviation duties tests positive for alcohol or drugs?

D. Miscellaneous

D 1. Should the FAA include within the scope of a proposed rule all authorized persons performing safety-sensitive maintenance functions on aircraft operated by part 121 air carriers in accordance with 14 CFR 43.17? Please include the rationale for why such personnel should or should not be subject to testing in any comment.

IV. Regulatory Notices and Analyses

A. Regulatory Evaluation

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 questions about the economic impacts of a future proposed rule.

Congress mandated that the FAA propose a rule requiring that all employees of part 145 repair stations who perform safety-sensitive maintenance functions on part 121 air carriers' aircraft be subject to an alcohol and drug testing program that has been determined acceptable by the Administrator and is consistent with the applicable laws of the country in which the repair station is located. This mandate requires the FAA to propose drug and alcohol testing for employees of part 145 repair stations located outside the United States who perform safety-sensitive maintenance functions on aircraft operated by part 121 air carriers. The FAA understands that the implementation of such a regulation would impose costs on industry, the FAA, and perhaps other parties.

The FAA might also extend this testing requirement to include all authorized persons performing safety-sensitive maintenance functions on aircraft operated by part 121 air carriers in accordance with 14 CFR § 43.17. It is very difficult, however, for the FAA to reliably estimate such costs at this time, given the limited information about other countries' relevant laws and regulations, existing drug and alcohol testing programs in other countries, the actual and potential costs associated with conducting drug and alcohol testing in other countries (which is expected to vary), the cost of establishing testing programs in countries where they do not currently exist, and other relevant information. To help gauge the economic impact of a proposed rule, the FAA is requesting

information from industry, as well as from the government of countries as described below. For all cost questions in this "Regulatory Notices and Analyses" section, please note who bears or would bear the costs (e.g., the employee; the air carrier for whom work is performed; the covered maintenance provider, a regulatory authority, other (please specify)) in any response provided.

In January 2006, the FAA issued a final rule entitled *Antidrug and Alcohol Misuse Prevention Programs for Personnel Engaged in Specified Aviation Activities* (71 FR 1666). That rule amended the FAA's regulations governing drug and alcohol testing in the United States to clarify that each person who performs a safety-sensitive function for a regulated employer by contract, including by subcontract at any tier, is subject to testing. Consequently, the regulatory evaluation for that final rule (hereinafter referred to as the "2005 Regulatory Evaluation"), which was published in Docket No.: FAA-2002-11301, addresses costs associated with drug and alcohol testing in the United States.

The FAA is providing information from the 2005 Regulatory Evaluation to provide the public with an understanding of the types and level of detail of information needed to accurately estimate the economic impact of a rule for drug and alcohol testing of employees of covered maintenance providers who perform safety-sensitive maintenance functions on aircraft operated by part 121 air carriers. The FAA understands that the costs associated with drug and alcohol testing are likely to be different outside the United States and may vary from country to country. The FAA also understands that the specific details of drug and alcohol testing programs likely vary from country to country; however, the FAA expects that, for any drug and alcohol testing program, there will be costs associated with the testing process, training and education, developing and maintaining a testing program, and keeping (and possibly submitting) any documentation that may be required by national regulatory authorities or as part of a voluntary program's policies. The FAA requests that commenters also provide information about any other costs that may be relevant. The FAA is interested in data at the national level, from the members of associations, and from specific companies' programs. There were a number of basic assumptions that the FAA made in the 2005 Regulatory Evaluation. The FAA assumed the following:

- Maintenance providers affected by that rule would develop and implement their own programs, instead of being covered under another company's program or using a service agent with already-established procedures.

- An additional 2.5% of maintenance workers would be subject to the antidrug and alcohol misuse prevention programs under that rule.

- The number of employees in the maintenance sector grows at 1.5% per year.

- There would be two supervisors per contractor and that the attrition rate for mechanics was approximately 10% per year.

The FAA requests comments on these assumptions.

The FAA also assumed the following values:

- Price of a drug test—\$45;
- Price of an alcohol test—\$34;

- Time for a drug test (hours)—0.75;
- Time for an alcohol test (hours)—0.75;

- One instructor for every 20 supervisors and/or employees to be trained

- Maintenance employee salary—\$33.07/hour;

- Maintenance supervisor salary—\$39.68/hour;

- Instructor—\$36.37/hour;

- Clerical—\$18.62/hour;

The FAA requests comments on these assumptions.

Testing Costs

All employees who are subject to drug and alcohol testing under FAA regulations in the United States are subject to the following types of tests: pre-employment (for drugs only), random, post-accident, reasonable cause/suspicion, return-to-duty, and

follow-up. The 2005 Regulatory Evaluation considered the cost of testing to include the actual cost of the test, as well as the cost of the employee's time.

Please answer the following questions.

RE 1. For each year of the last 10 years, please provide the number of (a) drug and (b) alcohol tests conducted on aviation personnel who perform safety-sensitive functions and the number of positive tests, regardless of whether maintenance personnel are currently tested under the particular program described. If maintenance personnel are currently tested, please provide the number of (a) drug and (b) alcohol tests conducted on maintenance personnel that perform safety-sensitive functions and the number of positive tests for such personnel separately. For an example of the type of data that the FAA seeks, see the table below from the 2005 Regulatory Evaluation.

Alcohol-Related Testing Results (Maintenance Personnel)	1996	1997	1998	1999	2000	2001	2002	2003
NUMBER OF TESTS	33,743	37,739	16,240	23,892	24,696	24,683	22,447	20,560
NUMBER OF POSITIVE RESULTS OF VIOLATIONS	82	75	61	48	53	71	49	45
PERCENT OF TESTS INVOLVING VIOLATIONS	0.24%	0.20%	0.38%	0.20%	0.21%	0.29%	0.22%	0.22%
Drug-Related Testing Results (Maintenance Personnel)						2001	2002	2003
NUMBER OF TESTS						85,993	67,694	68,589
NUMBER OF POSITIVE RESULTS						1,148	824	871
PERCENT OF TESTS THAT WERE POSITIVE						1.33%	1.22%	1.27%

RE 2. What types of testing are required for (a) drugs and (b) alcohol (e.g., pre-employment, post-accident, reasonable cause/suspicion, random, return-to-duty, follow-up, other (please specify))?

RE 3. What types of personnel are subject to (a) drug and (b) alcohol testing in the relevant country, company, or among the members of the association (e.g., pilots, flight attendants, air traffic controllers, flight dispatchers, maintenance personnel, other (please specify))?

RE 4. Is drug and alcohol testing currently conducted in the relevant country? If not, how would a requirement to drug and alcohol test be met (i.e. travel to a different country, implement a testing program within the relevant country, or other (please

specify)))? If traveling to another country, what is the distance from the relevant country? How much time will be spent traveling?

RE 5. What is the cost of (a) the drug test and (b) the alcohol test per person? Do or would the costs differ for different categories of tests (i.e., pre-employment, post-accident, reasonable cause/suspicion, random, periodic, return-to-duty, follow-up, or other (please specify))? How long does it take for an employee to complete each of these tests? If screening tests for (a) drugs or (b) alcohol are or would be conducted, followed by confirmatory testing when the screening test is positive, what are or would be the costs associated with conducting (a) the screening test and (b) the confirmatory test?

RE 6. How many maintenance personnel in the relevant country or in a particular company or group of companies perform safety-sensitive maintenance functions? How many of them perform safety-sensitive maintenance functions on aircraft operated by part 121 air carriers (and are not directly employed by such air carriers)? How many are subject to drug and alcohol testing?

RE 7. How many new employees are hired to perform safety-sensitive maintenance functions per year? How many maintenance employees who perform safety-sensitive functions leave per year? The FAA will need to be able to estimate testing costs in future years. See the table below for an example from the 2005 Regulatory Evaluation.

2005 Regulatory Evaluation

Forecasted Testing Costs											
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total
Maintenance Workers - Total	199,203	202,191	205,224	208,302	211,427	214,598	217,817	221,084	224,400	227,766	
Maintenance Workers - Affected by this rulemaking	4,980	5,055	5,131	5,208	5,286	5,365	5,445	5,527	5,610	5,694	
Alcohol Misuse Testing											
Pre-employment	18	19	19	19	19	20	20	20	21	21	196
Random	498	506	513	521	529	537	545	553	561	569	5,332
Post-Accident	2	3	3	3	3	3	3	3	3	3	29
Reasonable Cause	2	3	3	3	3	3	3	3	3	3	29
Return to Duty	2	2	2	2	2	2	2	2	2	2	20
Follow-Up - Current Year	12	12	12	12	12	13	13	13	13	13	125
Follow-Up - Next Year	0	12	12	12	12	12	13	13	13	13	112
Total Alcohol Tests	534	557	564	572	580	590	599	607	616	624	5,843
Drug Testing											
Pre-employment	4,980	933	947	961	975	990	1,004	1,020	1,035	1,050	13,895
Random	1,245	1,264	1,283	1,302	1,322	1,341	1,361	1,382	1,403	1,424	13,327
Post-Accident	5	5	5	5	5	5	5	5	5	5	50
Reasonable Cause	8	8	8	8	8	8	8	9	9	9	83
Return to Duty	8	8	9	9	9	9	9	9	9	10	89
Follow-Up - Current Year	41	42	42	43	44	44	45	46	46	47	440
Follow-Up - Next Year	0	33	33	34	34	35	35	36	37	37	314
Total Drug Tests	6,287	2,293	2,327	2,362	2,397	2,432	2,467	2,507	2,544	2,582	28,198
Cost of Alcohol Testing											
Total Tests	534	557	564	572	580	590	599	607	616	624	5,843
Cost of Test	\$18,156	\$18,938	\$19,176	\$19,448	\$19,720	\$20,060	\$20,366	\$20,638	\$20,944	\$21,216	\$198,662
Cost of Employee's Time	\$13,553	\$14,137	\$14,310	\$14,509	\$14,712	\$14,961	\$15,189	\$15,387	\$15,611	\$15,814	\$148,183
Total Cost	\$31,709	\$33,075	\$33,486	\$33,957	\$34,432	\$35,021	\$35,555	\$36,025	\$36,555	\$37,030	\$346,845
Cost of Drug Testing											
Total Tests	6,287	2,293	2,327	2,362	2,397	2,432	2,467	2,507	2,544	2,582	28,198
Cost of Test	\$282,915	\$103,185	\$104,715	\$106,290	\$107,865	\$109,440	\$111,015	\$112,815	\$114,480	\$116,190	\$1,268,910
Cost of Employee's Time	\$159,564	\$58,196	\$59,042	\$59,912	\$60,800	\$61,669	\$62,557	\$63,552	\$64,471	\$65,434	\$715,197
Total Cost	\$442,479	\$161,381	\$163,757	\$166,202	\$168,665	\$171,109	\$173,572	\$176,367	\$178,951	\$181,624	\$1,984,107

RE 7. What is or would be the annual cost per person of each category of staff required to conduct testing (collection personnel, laboratory personnel, other (please specify))?

Training and Education Costs

In the United States, for each drug and alcohol testing program, the employer must train employees and supervisors on the effects and consequences of drug use on personal health, safety, and work environment, as well as the manifestations and behavioral cues that may indicate drug use and abuse. The regulations do not specify the amount of time associated with this training; in the 2005 Regulatory Evaluation, the FAA assumed 30 minutes.

Under current regulations, supervisors who will make reasonable cause/suspicion determinations must receive at least 60 minutes for each program (for a total of 120 minutes). Supervisors must also receive recurrent training under the FAA's drug testing

rules. The rules do not say when the recurrent training must occur or how long it must be; however, the FAA recommends recurrent training every 12 to 18 months and that it include an element on alcohol testing. For the 2005 Regulatory Evaluation, the FAA assumed that the recurrent training occurs every 12 months and takes 60 minutes.

Please answer the following questions.

RE 8. What are or would be the initial and recurrent training and education costs, on a per person basis? For:

- Employees subject to testing,
- Supervisors,

c. Persons authorized to determine whether there is reasonable cause/suspicion to believe that an employee may be under the influence of alcohol or drugs while performing, or within a certain amount of time before or after performing, a safety-sensitive function and that the employee should be tested on that basis,

- Specimen collectors,

e. Persons responsible for analyzing specimens for alcohol, drugs, or their metabolites,

f. Persons involved in determining or recommending the appropriate course of treatment and/or education for an employee who has tested positive for drugs or alcohol,

g. Other personnel involved in the drug or alcohol testing program (please specify)?

RE 9. How many personnel in category (g) of question RE8 receive or would receive (1) initial and (2) recurrent training and/or education annually?

RE 10. What was or would be the cost of developing any necessary training program initially, including materials, and what is or would be the annual cost, including materials, of maintaining it? What types of training materials are or would be required?

RE 11. What are or would be the annual costs of the staff required to conduct training? How many staff would be required to conduct training?

RE 12. How often is/must/would recurrent training be conducted?

Program Development and Maintenance Costs

Under the rule for which the 2005 Regulatory Evaluation was conducted, it was assumed that each affected maintenance provider would have to devote resources to developing drug and alcohol testing programs. In addition, each affected maintenance provider would have to spend time to produce information required to either obtain an operations specification for its part 145 certificate or register its drug and alcohol program with the FAA. At the FAA, the submitted information would have to be processed and entered into the appropriate database.

In calculating program development costs in the 2005 Regulatory Evaluation, the FAA assumed 16 hours for start-up program development. The FAA estimated that, for affected maintenance providers that chose to register with the FAA, it would take each one 20 minutes at \$21 per hour to gather the required information and submit it to the FAA. At the FAA, the submitted information has to be processed. In the 2005 Regulatory Evaluation, the FAA estimated that an administrative assistant, an FG-7 being paid at about \$25.00 per hour, would enter this information into a database. The FAA assumed that administrative assistants would need 10 minutes to input the information.

Please answer the following questions.

RE 13. How much would it cost (besides training costs already addressed above or cost to do the actual testing) to develop a drug and alcohol testing program? What would be the annual program maintenance costs (besides training costs already addressed above)? What items are included in both of these types of costs?

RE 14. Is the drug and alcohol testing program regulated by an agency of a government? If so, how much time per year is required to prepare and maintain required documentation and submit information to the responsible regulatory authority? What information items must be submitted? How long does it take for the company to gather this information? How long does it take for the responsible regulatory authority to process the submission? Who at the responsible regulatory authority processes these submissions?

RE 15. How many submissions must be made per year?

RE 16. What are or would be the costs of staff required to evaluate employees who have tested positive for drugs or alcohol and to provide any needed education and/or treatment? What would the cost of treatment be, in terms of employees time and opportunity cost? How many such staff would be needed? What are or would be the other costs associated with any program of treatment and/or education?

RE 17. What are or would be the costs for a laboratory in the relevant country to obtain HHS, its equivalent, or more stringent certification, including both fees and the costs of any actions that would need to be taken to meet the applicable certification standards? Please specify the certification standards being used as a point of reference in any comments.

RE 18. Is shipping specimens to an existing HHS-certified or DOT approved laboratory a reasonable alternative? What would be the costs associated with packaging and shipping specimens to one of the existing HHS-certified laboratories for testing?

Annual Documentation Costs

The FAA's drug testing regulations require each company to document both the initial and recurrent training for supervisory personnel who make reasonable cause determinations. In the 2005 Regulatory Evaluation, the FAA assumed that the cost of this documentation is about \$1.30 per record, which included record creation, filing, and storage. The same sort of documentation is needed for the supervisors who determine whether reasonable suspicion exists concerning probable alcohol misuse. The FAA assumed the cost of this documentation is also about \$1.30 per record. The FAA's existing regulations require documentation of such things as:

- Training of employees in the requirements of the antidrug program;
- All reasonable cause/suspicion cases;
- If a post-accident alcohol test is not administered within 2 hours following the accident, the reasons the test was not promptly administered;
- If a post-accident alcohol test is not administered within 8 hours following the accident, the reasons the test was not promptly administered;

- Refusal to submit to a required drug or alcohol test (the company must also notify the FAA); and

- Medical Review Officer (MRO) reports of verified positive drug test results for employees holding airman medical certificates issued by the FAA under 14 CFR part 67. (Both the MRO and the company must also notify the FAA.)

Please answer the following questions.

RE 19. What are or would be the annual recordkeeping or other documentation costs associated with the drug and/or alcohol testing program?

RE 20. Who maintains or would maintain any required documentation (e.g., employer, government agency, other (please specify))?

RE 21. What documentation is or would be required to be maintained by and/or submitted to the responsible regulatory agency? How much time would be needed to prepare and/or submit the documentation?

RE 22. What is the format for recordkeeping?

Accident Prevention Benefits

The FAA indicated in the 2005 Regulatory Evaluation that it believed it was possible that illegal drug use or alcohol misuse by members of the aviation community may have contributed to additional accidents or incidents. The FAA acknowledged the fact that there had not been any aviation accidents directly attributed to a maintenance worker misusing or abusing drugs or alcohol.⁵ However, as the table below shows, maintenance employees had among the highest positive rates on alcohol and drug tests among aviation-related employees, so the connection between illegal drug use and alcohol misuse and maintenance-related accidents certainly could exist. The FAA stated that it was important to note that not only are maintenance workers rarely tested after an accident (only 0.05% and 0.09% of maintenance workers are administered post-accident alcohol and drug tests, respectively), but it would be difficult to directly tie poor maintenance work, due to inappropriate drug use or alcohol misuse, to an accident that may occur weeks or months later, particularly with the widespread use of contract workers at many different tiers.

⁵ That analysis was limited to maintenance workers because that was the population affected by that rulemaking.

	Percentage of Alcohol Violation Test (2001 – 2003)	Percentage of Positive Drug Test (2001-2003)
Flight Crew	0.11%	0.07%
Flight Attendants	0.39%	0.51%
Flight Instructors	0.08%	0.14%
Aircraft Dispatchers	0.21%	0.79%
Maintenance Personnel	0.24%	1.28%
Aviation Screeners	0.24%	2.09%
Ground Security Coordinators	0.22%	0.72%
Air Traffic Controllers	0.00%	0.52%
TOTAL	0.25%	0.99%

The 2005 Regulatory Evaluation indicated that, while there had been no documented aviation accidents in the United States in the time period analyzed that were directly attributed to misuse or abuse of drugs or alcohol by maintenance personnel, the FAA believed it was possible that such misuse or abuse may have contributed to aviation-related accidents. The FAA believed it was prudent to base the estimated benefits of the final rule on avoiding one part 135 accidents over the next 10 years, thus avoiding a total of 5 fatalities and a destroyed or damaged airplane. The FAA estimated the benefits of avoided fatalities at \$15 million. This number of accidents, fatalities, and destroyed airplanes was less than 1% of all maintenance-related accidents that had occurred; the FAA considered these benefits to be reasonable. The total benefits in the 2005 regulatory evaluation were calculated by assuming an equally likely chance of avoiding these accidents in each of the next 10 years. Total benefits summed to \$15.07 million (\$10.59 million, discounted).

Please answer the following questions.

RE 22. What benefits has the relevant country/company seen from drug and alcohol testing?

RE 23. Are you aware of any accidents in which drug or alcohol misuse by safety-sensitive aviation personnel (e.g. pilots, flight attendants, maintenance personnel, air traffic controllers, flight dispatchers, other (please specify)) may have caused or contributed to the accident? Please describe the circumstances and identify the type of safety-sensitive personnel whose drug or alcohol misuse may have caused or contributed to the accident. Were there any fatalities, injuries, or damage to aircraft? If so, please describe. How many confirmed positive drug and alcohol tests occur annually in the country/company?

RE 24. Have industry participants experienced a savings in insurance premiums as a result of drug and alcohol testing?

B. International Compatibility

In keeping with the United States' obligations under the Chicago Convention, it is FAA policy to conform to ICAO Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that exactly correspond to the regulations being considered for proposal, as ICAO neither requires nor recommends that Member States implement testing of aviation personnel with safety-sensitive responsibilities for alcohol or drugs. As discussed in the Background section of this preamble, however, there are a number of ICAO standards and recommended practices that address the misuse of drugs and alcohol by such personnel and recognize the potential hazard that such substance misuse may pose to aviation safety.

C. 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 ANPRM qualifies for the categorical exclusion identified in paragraph 312d and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 12866, Regulatory Planning and Review, Executive Order 13563, Improving Regulation and Regulatory Review and DOT Regulatory Policies and Procedures

The FAA is soliciting comments on the potential costs and benefits of the

initiatives in the ANPRM. This ANPRM has been drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. This ANPRM has been reviewed by the Office of Management and Budget and is considered "significant" under the Department of Transportation's Regulatory Policies and Procedures.

B. Executive Order 13132, Federalism

The FAA has analyzed this ANPRM under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would 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, would not have Federalism implications.

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

The FAA analyzed this ANPRM under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it would not be a "significant energy action" under the executive order and likely would not have a significant adverse effect on the supply, distribution, or use of energy.

VI. Additional Information

A. Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The Agency also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, or a

specific question posed by the FAA, and fully explain the rationale for any comment, include supporting data, if applicable. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time. The FAA requests that all comments be submitted in English.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this ANPRM. Before acting on this ANPRM, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The Agency may change its potential proposals in light of the comments it receives.

Proprietary or Confidential Business Information: Do not file proprietary or confidential business information in the docket. Such information must be sent or delivered directly to any of the persons identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD ROM, mark the outside of the disk or CD ROM, and identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), if the FAA is aware of proprietary information filed with a comment, the Agency does not place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

B. Availability of Rulemaking Documents

Electronic copies of rulemaking documents may be obtained from the Internet by—

1. Searching the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visiting the FAA's Regulations and Policies Web page at http://www.faa.gov/regulations_policies or
3. Accessing the Government Printing Office's Federal Digital System at <http://www.gpo.gov/fdsys/>.

Copies may also be obtained by sending a request to the Federal

Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this ANPRM, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced in item (1) above.

Issued in Washington, DC, under the authority set forth in 49 U.S.C. 44733 on: March 5, 2014.

James R. Fraser,
Federal Air Surgeon.

[FR Doc. 2014-05653 Filed 3-14-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA-2014-N-0108]

New Animal Drug Applications; Confidentiality of Data and Information in a New Animal Drug Application File

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to amend its regulation regarding the confidentiality of data and information in and about new animal drug application files to change when certain approval-related information would be disclosed by the Agency. This change would ensure that the Agency is able to update its list of approved new animal drug products within the statutory timeframe. It would also permit more timely public disclosure of approval-related information, increasing the transparency of FDA decision making in the approval of new animal drugs.

DATES: Submit either electronic or written comments by June 2, 2014. If FDA receives any significant adverse comments, the Agency will publish a document in the **Federal Register** withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2014-N-0108, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand Delivery/Courier (for paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2014-N-0108 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Scott Fontana, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0656.

SUPPLEMENTARY INFORMATION:

I. Background

Section 512(i) (21 U.S.C. 360b(i)) was added to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by the Animal Drug Amendments of 1968 (Pub. L. 90-399). Section 512(i) requires the conditions and indications of use of a new animal drug to be published in the **Federal Register** upon approval of a new animal drug application (NADA) filed under section 512(b) of the FD&C Act.

In 1974, FDA revised its regulations regarding the confidentiality of information in applications in § 135.33a (21 CFR 135.33a) to include provisions of the Freedom of Information Act (Pub. L. 89-487). That revision established that public disclosure by the Agency of certain data and information in an NADA file could not occur before the **Federal Register** notice of approval