

2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

#### The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

#### PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

**Bombardier, Inc. (Formerly de Havilland, Inc.):** Docket No. FAA-2008-1083; Directorate Identifier 2008-NM-130-AD.

#### Comments Due Date

(a) We must receive comments by November 10, 2008.

#### Affected ADs

(b) None.

#### Applicability

(c) This AD applies to Bombardier Model DHC-8-400, DHC-8-401, and DHC-8-402 airplanes, certificated in any category, Serial numbers 4003, 4004, 4006, and 4008 through 4184 inclusive.

#### Subject

(d) Air Transport Association (ATA) of America Code 32: Landing Gear.

#### Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

“There have been several cases reported where the landing gear did not retract after take-off. Subsequent investigation revealed this was caused by fatigue failure of the nose landing gear electrical harness. In conjunction with one engine being inoperable, this could, in certain operating conditions, affect continued safe flight and landing.”

“This directive mandates incorporation of new weight-on-wheels (WOW) and steering harnesses that have a new conduit construction.”

#### Actions and Compliance

(f) Unless already done, do the following actions.

(1) Within 2,500 flight hours after the effective date of this AD, replace the WOW and steering harnesses by incorporating Modsum 4-126401, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84-32-51, Revision ‘B,’ dated December 17, 2007.

(2) Actions done before the effective date of this AD in accordance with Bombardier Service Bulletin 84-32-51, dated August 16, 2007, or Revision ‘A,’ dated August 22, 2007, are acceptable for compliance with the corresponding requirements of this AD.

#### FAA AD Differences

**Note:** This AD differs from the MCAI and/or service information as follows: No differences.

#### Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, Systems and Flight Test Branch, ANE-172, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Wing Chan, Aerospace Engineer, Systems and Flight Test Branch, ANE-172, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228-7311; fax (516) 794-5531. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) Reporting Requirements: For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

#### Related Information

(h) Refer to MCAI Canadian Airworthiness Directive CF-2008-22, dated June 24, 2008, and Bombardier Service Bulletin 84-32-51, Revision ‘B,’ dated December 17, 2007, for related information.

Issued in Renton, Washington, on October 2, 2008.

#### Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-24161 Filed 10-9-08; 8:45 am]

**BILLING CODE 4910-13-P**

#### DEPARTMENT OF THE TREASURY

##### Internal Revenue Service

#### 26 CFR Part 54

[REG-123829-08]

RIN 1545-B102

#### DEPARTMENT OF LABOR

##### Employee Benefits Security Administration

#### 29 CFR Part 2590

RIN 1210-AB27

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CMS-4137-NC]

#### 45 CFR Parts 144, 146, and 148

RIN 0938-AP37

#### Request for Information Regarding Sections 101 Through 104 of the Genetic Information Nondiscrimination Act of 2008

**AGENCIES:** Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

**ACTION:** Request for Information.

**SUMMARY:** This document is a request for comments regarding issues under sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008 (GINA). The Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) have received inquiries from the public on a number of issues under these provisions and are welcoming public comments in advance of future rulemaking.

**DATES:** Comments must be submitted on or before December 9, 2008.

**ADDRESSES:** Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

*Department of Labor.* Comments to the Department of Labor by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *E-mail:* [E-OHPSCA.EBSA@dol.gov](mailto:E-OHPSCA.EBSA@dol.gov).
- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security

Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: GINA Comments.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210, including any personal information provided.

*Department of HHS.* Comments to the Department of HHS, identified by CMS-4137-NC, by one of the following methods:

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

- *Mail:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4137-NC, P.O. Box 8017, Baltimore, MD 21244-8010.

- *Hand or courier delivery.* Comments may be delivered to either 7500 Security Boulevard, Baltimore, MD 21244-1850 or Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. For delivery to Baltimore, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. For delivery to Washington, because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the comments being filed.

All submissions submitted to HHS will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters for the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786-7195.

*Internal Revenue Service.* Comments to the IRS, identified by REG-123829-08, by one of the following methods:

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

- *Mail:* CC:PA:LPD:PR (REG-123829-08), Room 5205, Internal Revenue

Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

- *Hand or courier delivery:* Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-123829-08), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

**FOR FURTHER INFORMATION CONTACT:**

Amy Turner, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Adam Shaw, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (877) 267-2323 extension 61091.

*Customer Service Information:* Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws, including the nondiscrimination protections, may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, individuals may request a copy of CMS's publication entitled "Protecting Your Health Insurance Coverage" by calling 1-800-633-4227.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Genetic Information Nondiscrimination Act of 2008 (GINA) was enacted on May 21, 2008 (Pub. L. 110-233). Title I of GINA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), the Internal Revenue Code of 1986 (Code), and the Social Security Act (SSA) to prohibit discrimination in health coverage based on genetic information. Sections 101 through 104 of GINA apply to employment-based health coverage, individual market health insurance, and Medicare supplemental (MedSup or Medigap) coverage. The new requirements were added to Part 7 of Subtitle B of Title I of ERISA, Title XXVII of the PHS Act, Subtitle K of the Code, and section 1882 of the SSA.

GINA prohibits group health plans and health insurance issuers (that is, insurance companies or health maintenance organizations (HMOs)) in the group market from using genetic information to adjust premium or

contribution amounts for the group covered under the plan. Plans and issuers in the group market are still allowed to increase the premium rate for an employer based on the manifestation of a disease or disorder of an individual enrolled in the plan, but they are prohibited from using the manifested disease or disorder of one individual as genetic information about other group members to further increase the premium.

In the individual market, health insurance issuers are prohibited from using genetic information to determine individual eligibility or premium rates, although they are allowed (to the extent consistent with other provisions of law) to use information about a manifestation of a disease or disorder to determine eligibility or premium rates for an individual who is covered or would be covered by a policy. Individual market health insurance issuers are also prohibited from using genetic information in imposing a preexisting condition exclusion, although a manifestation of a disease or disorder in an individual can be the basis for an exclusion. In the MedSup market, GINA prohibits issuers from denying or conditioning the issuance or effectiveness of a policy (including the imposition of any exclusion of benefits based on a preexisting condition) or discriminating in the pricing of the policy based on an individual's genetic condition. However, if otherwise permitted under section 1882 of the Social Security Act, the issuer can still impose such limitations based on a manifested disease of an individual who is covered or would be covered under the policy.

GINA also prohibits group health plans and health insurance issuers in the group, individual, and MedSup markets from requesting or requiring an individual or family member of an individual to undergo a genetic test. Plans and issuers are not precluded from obtaining and using the results of a genetic test to make a determination regarding payment, but they may only use the minimum amount of information necessary.

GINA includes a research exception under which a group health plan or a health insurance issuer in the group, individual, or MedSup market may request (but not require) a participant or beneficiary to undergo a genetic test if the following five conditions are met:

- The request is made in writing pursuant to research that complies with 45 CFR Part 46, or equivalent Federal regulations, and any applicable State or local law or regulations for the

protection of human subjects in research.

- The plan or issuer clearly indicates to each participant or beneficiary to whom the request is made that compliance is voluntary and non-compliance will have no effect on enrollment status or premium contribution amounts.

- None of the genetic information collected can be used for underwriting purposes.

- The plan or issuer notifies the appropriate Secretary in writing that it is conducting such research activities, including a description of the activities conducted.

- The plan or issuer complies with such other conditions as may be required by regulations for such activities.

Group health plans and health insurance issuers in the group, individual, and MedSupp markets are prohibited from requesting, requiring, or purchasing genetic information for underwriting purposes or prior to an individual's enrollment under a plan or policy. Plans and issuers are still allowed to collect (that is, to request, require, or purchase) health information that relates to the manifestation of a disease or disorder of an individual enrolled in a plan or who is covered by or would be covered by a policy issued in the individual or MedSupp market, and use it for permitted underwriting purposes with respect to that individual. Furthermore, an exception to the prohibition on requesting, requiring, or purchasing genetic information is included for collection of genetic information which is incidental to the request, requirement, or purchase of other information concerning an individual, provided it is not used for underwriting purposes.

GINA defines genetic information with respect to any individual as information about that individual's genetic tests, the genetic tests of family members of the individual, and the manifestation of a disease or disorder in family members of the individual. The term genetic information also includes an individual's request for, or receipt of, genetic services, but does not include information about the sex or age of any individual. Genetic services are further defined as a genetic test, genetic counseling (which includes obtaining, interpreting, or assessing genetic information), or genetic education. A genetic test is defined for purposes of Title I of GINA as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. The term is not meant to include an

analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes, or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that a health care professional with appropriate training and expertise could reasonably detect. Definitions of family member and underwriting purposes are also included, as well as provisions clarifying that references to genetic information concerning an individual include the genetic information of a fetus carried by a pregnant woman and of an embryo legally held by an individual utilizing an assisted reproductive technology.

The provisions of GINA are effective with respect to group health plans and health insurance issuers in the group market for plan years beginning after May 21, 2009. For health insurance issuers in the individual market, the provisions are effective with respect to health insurance coverage sold, issued, renewed, in effect, or operated in the individual market after May 21, 2009. For MedSupp coverage, States must incorporate the GINA provisions into their regulatory programs no later than July 1, 2009.

## II. Solicitation of Comments

### A. Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act

Executive Order 12866 requires an assessment of the costs and benefits of a significant rulemaking action and the alternatives considered, using the guidance provided by the Office of Management and Budget. These costs and benefits are not limited to the Federal government, but pertain to the affected public as a whole. Under Executive Order 12866, a determination must be made whether implementation of GINA sections 101 through 104 will be economically significant. A rule that has an annual effect on the economy of \$100 million or more is considered economically significant.

In addition, the Regulatory Flexibility Act may require the preparation of an analysis of the economic impact on small entities of proposed rules and regulatory alternatives. An analysis under the Regulatory Flexibility Act must generally include, among other things, an estimate of the number of small entities subject to the regulations (for this purpose, plans, employers, and issuers and, in some contexts small governmental entities), the expense of the reporting and other compliance requirements (including the expense of using professional expertise), and a

description of any significant regulatory alternatives considered that would accomplish the stated objectives of the statute and minimize the impact on small entities. The Departments seek additional information from small entities regarding any special problems they might encounter in implementing the requirements of sections 101 through 104 of GINA and any regulatory guidance that might minimize those problems.

The Paperwork Reduction Act requires an estimate of how many "respondents" will be required to comply with any "collection of information" aspects of the regulations and how much time and cost will be incurred as a result. A collection of information includes record-keeping, reporting to governmental agencies, and third-party disclosures.

The Departments are requesting comments that may contribute to the analyses that will be performed under these requirements, both generally and with respect to the following specific areas:

- (i) What policies, procedures, or practices of group health plans and health insurance issuers may be impacted by regulations under GINA? What direct or indirect costs would result? What direct or indirect benefits would result? Which stakeholders will be impacted by such benefits and costs?
- (ii) Are there unique costs and benefits for small employers or small plans? What special consideration, if any, is needed for small employers or small plans?

### B. Comments Regarding Regulatory Guidance

The Departments are seeking comments to aid in the development of regulations regarding sections 101 through 104 of GINA. To assist interested parties in responding, this request for information describes specific areas in which the Departments are particularly interested; however, the Departments also request comments and suggestions concerning any area or issue pertinent to the development of regulations.

#### Specific Areas in Which the Departments Are Interested Include the Following

1. To what extent do group health plans and health insurance issuers currently use genetic information, such as family medical history, and for what purposes? For example, is genetic information currently used for group rating purposes, or for purposes of a wellness program that otherwise

complies with HIPAA's nondiscrimination requirements?

2. How do plans and issuers currently obtain genetic information (for example, through health risk assessments, the Medical Information Bureau, or other entities under common control)?

3. Under what circumstances do plans or issuers currently request or require an individual to take a genetic test?

4. Under what circumstances do plans or issuers currently ask for the results of a genetic test in order to make a determination regarding payment of benefits? What is the minimum amount of information necessary for a plan or issuer to make a determination under such circumstances?

5. What types of research do plans or issuers currently conduct or support using genetic tests?

6. Would a model notice be helpful to facilitate disclosure to plan participants and beneficiaries regarding a plan's or issuer's use of the research exception? In this regard, what information would be most helpful to participants and beneficiaries?

7. Similarly, would a model form be helpful for reporting to the Departments by a plan or issuer claiming the research exception? In this regard, what information should plans and issuers report?

8. When might genetic information be collected incidentally?

9. What terms or provisions (such as genetic information, genetic test, genetic services, or underwriting) would require additional clarification to facilitate compliance? What specific clarifications would be helpful?

Signed at Washington, DC this 4th day of June, 2008.

**Alan Tawshunsky,**

*Deputy Division Counsel/Deputy Associate Chief Counsel, Tax Exempt and Government Entities, Internal Revenue Service, Department of the Treasury.*

Signed at Washington, DC this 5th day of June, 2008.

**W. Thomas Reeder,**

*Benefits Tax Counsel, Department of the Treasury.*

Signed at Washington, DC this 2nd day of October, 2008.

**Bradford P. Campbell,**

*Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.*

Dated: June 30, 2008.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. E8-24194 Filed 10-9-08; 8:45 am]

BILLING CODES 4830-01-P; 4510-29-P; 4120-01-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 158 and 161

[EPA-HQ-OPP-2008-0110; FRL-8383-6]

#### Data Requirements for Antimicrobial Pesticides; Notice of Public Workshop

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; notice of public workshop.

**SUMMARY:** EPA is convening a public workshop to explain the provisions of its recently proposed rule to update and revise the data requirements for registration of antimicrobial pesticides. The workshop is intended to provide an opportunity for members of the public to ask questions about the proposed rule and seek any clarification they believe may assist them in submitting comments to the docket for the proposed rule. Any person wishing to comment on the proposed rule must submit any comments to the docket within the timeframe set forth in the Notice of Proposed Rulemaking.

**DATES:** The meeting will be held on November 6, 2008, from 8:30 a.m. to 4:00 p.m.

To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

**ADDRESSES:** The meeting will be held at the Office of Pesticide Programs (OPP), First Floor Conference Center, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

To facilitate the Agency's planning, your intention to participate in the Antimicrobials Workshop, may be submitted to the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### FOR FURTHER INFORMATION CONTACT:

Kathryn Boyle, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703.305.6304; fax number: 703.305.5884; e-mail address: [boyle.kathryn@epa.gov](mailto:boyle.kathryn@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be affected by this action if you are a producer of pesticide products (NAICS code 32532), antifoulants (NAICS code 32551), antimicrobial pesticides (NAICS code 32561) or wood

preservatives (NAICS code 32519), importers of such products, or any person or company who seeks to register an antimicrobial, antifoulant coating, ballast water treatment, or wood preservative pesticide or to obtain a tolerance for such a pesticide. This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed above could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, please contact Norm Cook, Chief of the Risk Assessment and Science Support Branch in the Antimicrobials Division of the Office of Pesticide Programs at 703-308-8253 or via email, [cook.norm@epa.gov](mailto:cook.norm@epa.gov).

###### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket ID number EPA-HQ-OPP-2008-0110. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>.

##### II. Background

EPA is convening a public workshop to explain the proposed revisions to the data requirements for the registration of antimicrobial pesticides. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), anyone seeking to register a pesticide product is required to provide information to EPA to demonstrate that their products can be used without posing "unreasonable adverse effects on the environment" as defined by FIFRA section 2(bb).

The public workshop will include presentations by staff from the Antimicrobial, and the Field and