The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by removing amendment 39–10147 (62 FR 50861, September 29, 1997), and by adding a new airworthiness directive (AD), to read as follows:

De Havilland, Inc.: Docket 98–NM–70–AD. Revises AD 97–20–10, Amendment 39–10147.

Applicability: Model DHC–8–100, –200, and –300 series airplanes, serial numbers 3 through 472 inclusive, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent simultaneous power loss to both attitude and heading reference systems (AHRS), which could result in reduced controllability of the airplane, accomplish the following:

(a) Within 400 hours time-in-service after November 3, 1997 (the effective date of AD 97–20–10, amendment 39–10147), modify the AHRS's, in accordance with Bombardier Alert Service Bulletin S.B. A8–34–117, Revision 'C', dated February 14, 1997.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Canadian airworthiness directive CF–97–01R2, dated August 13, 1997.

Issued in Renton, Washington, on June 9, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–15885 Filed 6–15–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. 98N–0361]

Administrative Practices and Procedures; Internal Agency Review of Decisions; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations governing the review of agency decisions by inserting a statement that sponsors, applicants, or manufacturers of drugs (including biologics) or devices may request review of a scientific controversy by an appropriate scientific advisory panel, or an advisory committee. The agency is taking this action to clarify the availability of review of scientific controversies by such advisory panels or committees. This proposed rule is a companion document to a direct final rule published elsewhere in this issue of the **Federal Register**. If FDA receives any significant adverse comment, the direct final rule will be withdrawn, and the comments will be considered in the development of a final rule using usual notice and comment rulemaking based on this proposed rule.

DATES: Comments must be received on or before August 31, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Suzanne M. O'Shea, Office of the Chief Mediator and Ombudsman (HF–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

SUPPLEMENTARY INFORMATION:

I. Discussion

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115). Section 404 of FDAMA amends the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by adding a new provision, Dispute Resolution (section 562 of the act (21 U.S.C. 360bbb-1)). Under the dispute resolution provision, FDA is to determine the existence of procedures

for sponsors, applicants, and manufacturers of drugs (including biologics) or devices to request review of scientific controversies. Where such procedures do not exist, FDA is directed to issue a regulation establishing a procedure by which a sponsor, applicant, or manufacturer of a drug or device may request review of a scientific controversy, including review by an appropriate scientific advisory panel as described in section 505(n) of the act[1] (21 U.S.C. 355(n)), or an advisory committee as described in section 515(g)(2)(B) of the act (21 U.S.C. 360e(g)(2)(B)).

FDA procedures currently provide mechanisms for sponsors, applicants, or manufacturers of drugs and devices to request review of all scientific controversies. Agency regulations and policy statements contain numerous procedures for obtaining review of scientific controversies affecting regulated products, including some that provide for review by an FDA advisory panel or committee. Moreover, any interested person[2] may obtain review of any agency decision by raising the matter with the supervisor of the employee who made the decision. If the issue is not resolved at the supervisor's level, the interested person may request that the matter be reviewed at the next higher supervisory level. This process may continue through the agency's chain of command (§ 10.75 (21 CFR 10.75)).

Notwithstanding the existence of these dispute resolution mechanisms, FDA intends to amend § 10.75 in light of FDAMA, to clarify that sponsors, applicants, or manufacturers of a drug or device subject to the act, or a product covered by the Public Health Service Act (42 U.S.C. 262), may request review of scientific controversies by an appropriate scientific advisory committee. If this rule is adopted, FDA would recommend that sponsors, applicants, and manufacturers continue to use established mechanisms for obtaining review of scientific controversies prior to seeking review by an advisory committee. FDA recognizes however, that in appropriate circumstances, review by such an advisory panel or committee may provide FDA with useful advice and recommendations about how the agency may best resolve a controversy.

[1] FDA understands the term ''scientific advisory panel'' to mean a public advisory committee as discussed in 21 CFR part 14.

[2] An interested person, as defined in 21 CFR 10.3, is a person who submits a petition or comment or objection or otherwise asks to participate in an informal or formal administrative proceeding or court action. This definition of interested person includes a sponsor, applicant, or manufacturer of a drug or device.

II. Rulemaking Procedures

In the final rules section of this issue of the **Federal Register**, FDA is announcing the adoption of this amendment through direct final rulemaking procedures. FDA described its procedures for direct final rulemaking in the **Federal Register** of November 21, 1997 (62 FR 62466). This action is appropriate for direct final rulemaking because it is a noncontroversial amendment to FDA's regulations that is in accord with FDAMA. Furthermore, FDA anticipates no significant adverse comments. Consistent with FDA's procedures for direct final rulemaking, FDA will withdraw the direct final rule if it receives any significant adverse comment. If the direct final rule is withdrawn, FDA will consider all comments received to develop a final rule using the usual notice and comment rulemaking procedures based on this proposed rule.

FDA is providing a 75-day period for comment on this companion proposed rule, to run concurrently with the comment period for the direct final rule. This comment period begins on June 16, 1998, and ends on August 31, 1998. If FDA receives any significant adverse comment within the comment period, it intends to publish a document in the **Federal Register** to withdraw the direct final rule by September 29, 1998. If the direct final rule is withdrawn, FDA will follow its usual procedures for notice-and-comment rulemaking based on this proposed rule. If FDA does not receive any significant adverse comment, the agency will take no further action on this proposed rule. In that event, FDA will publish a document in the **Federal Register** by September 29, 1998, to confirm the October 29, 1998, effective date of the direct final rule. For additional information, see the direct final rule published in the final rules section of this issue of the **Federal Register**.

III. Analysis of Impacts

A. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

B. Economic Impact

In accordance with Executive Order 12866, FDA has carefully analyzed the economic effects of this rule and has determined that it is not a major rule as defined by the Executive Order.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this rule will have on small entities, including small businesses, and has determined that no significant economic impact on a substantial number of small entities will derive from this action.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Request for Comments

Interested persons may, on or before August 31, 1998, submit to the Dockets Management Branch (address above) written comments regarding this companion proposed rule, which will also be considered as comments on the direct final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 10 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 is revised to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–4161; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 10.75 is amended by adding a sentence at the end of paragraph (b) to read as follows:

§ 10.75 Internal agency review of decisions.

* * * * *

(b) * * * A sponsor, applicant, or manufacturer of a drug or device regulated under the act or the Public

Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act.

* * * * *

Dated: June 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15814 Filed 6–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[REG–110403–98]

RIN 1545–AW28

Federal Employment Tax Deposits—De Minimis Rule

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the deposits of Federal employment taxes. The text of those regulations also serves as the text of these proposed regulations.

DATES: Written comments and requests for a public hearing must be received by September 14, 1998.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG–110403–98), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–110403–98), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC. Alternatively, taxpayers may submit comments electronically via the internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS internet site at http://www.irs.ustreas.gov/prod/tax__regs/comments.html.

FOR FURTHER INFORMATION CONTACT: Concerning submissions, Michael Slaughter, (202) 622–7180; concerning the regulations, Vincent Surabian, (202) 622–4940 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Employment Tax and Collection of Income Tax at Source Regulations (26 CFR part 31) relating to section 6302. The temporary regulations change the de minimis rule for the deposit of Federal employment taxes. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested by any person that timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information: The principal author of these regulations is Vincent Surabian, Office of Assistant Chief Counsel (Income Tax & Accounting). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 31 is proposed to be amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Paragraph 1. The authority citation for part 31 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. In § 31.6302–1, paragraph (f)(4) is revised to read as follows:

§ 31.6302–1 Federal tax deposit rules for withheld income taxes and taxes under the Federal Insurance Contributions Act (FICA) attributable to payments made after December 31, 1992.

* * * * *

(f) * * *

(4) [The text of proposed § 31.6302–1(f)(4) is the same as the text of § 31.6302–1T(f)(4)].

* * * * *

Michael P. Dolan,

Deputy Commissioner of Internal Revenue.

[FR Doc. 98–15985 Filed 6–15–98; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CCD 08–98–018]

RIN 2115–AE46

Special Local Regulations; Eighth Coast Guard District Annual Marine Events

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise Table 1 to 33 CFR 100.801, the list of annual marine events that occur within the Eighth Coast Guard District. This proposed revision will also result the Eighth Coast Guard District's absorption of the territories previously encompassed by Second the Coast Guard District.

DATES: Comments must be received on or before August 17, 1998.

ADDRESSES: Comments should be mailed to Commander (dl), Eighth Coast Guard District, 501 Magazine Street, New Orleans, LA 70130–3396. The comments will be available for inspection and copying at the District Legal Office, Room 1311, Hale Boggs Federal Building, 501 Magazine Street, New Orleans, LA. Office hours are