Action	Compliance Time	Procedures
(2) Modify the windshield deicing system wires and circuit breakers. You may remove the POH temporary revision referenced in paragraph (d)(1) of this AD after accomplishing this modification..	Within the next 12 months after February 24, 2001 (the effective date of this AD), unless already accomplished..	In accordance with the modification procedures in the Accomplishment Instructions section of Pilatus Service Bulletin No. 30–006, dated May 22, 2000.
(3) Do not install, on any affected airplane, P/N 959.81.10.107 LH and P/N 959.81.10.108 RH windshields (PPG P/N NP172121–5 LH and NP172121–6 RH or FAA-approved equivalent part numbers), without incorporating the modification required in paragraph (d)(2) of this AD..	As of February 24, 2001 (the effective date of this AD.).	Not applicable.

Note 1: Temporary Revision No. 21 to PC–12 Pilot's Operating Handbook, Report No. 01973–001, Section 2, Windshield Heater Operation 101–320, Issued: May 19, 2000, eliminates the need for Temporary Revision No. 14 in the POH.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, 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 (e) 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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Roman T. Gabrys, Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone: (816) 329–4141; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Pilatus Service Bulletin No. 30–006, dated May 22, 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective ?* This amendment becomes effective on February 24, 2001.

Note 3: The subject of this AD is addressed in Swiss AD HB 2000–393, dated September 6, 2000.

Issued in Kansas City, Missouri, on December 22, 2000.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–184 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. 00N–1634]

Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its administrative regulations governing the public disclosure of written information for consideration by an advisory committee at an advisory committee meeting. This action amends the regulations to state that the written information for consideration by an advisory committee at a committee meeting is available for public disclosure, whenever practicable, before or at the time of the meeting. FDA is taking this action to reflect current FDA policy in conformance with applicable law. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule.

DATES: This rule is effective May 23, 2001. Submit written comments by March 26, 2001. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before April 23, 2001, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation notice in the **Federal Register**. If timely significant adverse comments are received, the agency will publish a document of significant adverse comments in the **Federal Register** and withdraw this direct final rule before April 23, 2001.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Discussion

A. Background

Advisory committees provide independent advice and recommendations to FDA on scientific and technical matters related to products regulated by the agency. To assist committee members in preparing to discuss the issues that will be raised at a committee meeting, the agency and, in certain circumstances, affected members of the regulated industry prepare written background materials

for committee members. Generally, advisory committee members are provided these materials soon after they are completed, often weeks before a committee meeting.

FDA's advisory committees are established under the Federal Advisory Committee Act (5 U.S.C. app. 2) (the FACA). FDA's procedures for the administration of advisory committees are set forth in part 14 (21 CFR part 14). Section 14.75(a)(1) states that, unless it is otherwise exempt from disclosure, written information for consideration by the committee at the meeting should be available for public disclosure at the same time it is made available to the committee. As described below, FDA finds this provision for simultaneous disclosure unnecessary and detrimental to the advisory committee process. Therefore, FDA is amending this provision in its administrative regulations.

B. Rationale for the Rule

As interpreted by case law, the FACA requires that, whenever practicable and subject to any applicable exemption of the Freedom of Information Act (the FOIA) (5 U.S.C. 552), information prepared for or provided to an advisory committee be made publicly available before or at the time of the advisory committee meeting at which the information is used and discussed (see, e.g., *Food Chemical News* v. *Department of Health and Human Services*, 980 F.2d 1468 (D.C. Cir. 1992)). Therefore, FDA's provision for disclosing information to the public at the same time the information is provided to the advisory committee (§ 14.75(a)(1)) goes beyond the requirements of the FACA. The agency is not obligated under the FACA to provide the materials to the public at the same time they are provided to the advisory committee.

Under § 14.75(b)(1), the public disclosure provision of § 14.75(a)(1) is subject to FDA's regulations in part 20 (21 CFR part 20). The regulations in part 20 describe the agency's policies and procedures for disclosing information to the public under the FOIA. Information that generally may be released to the public, including information described in § 14.75(a)(1), may not be released if it falls within one or more of the exemptions described in part 20. Written materials provided to an advisory committee for consideration at a committee meeting often include information that is not made publicly available because the information is subject to one or more of the following exemptions: (1) Trade secrets and commercial or financial information that is privileged or confidential (§ 20.61); (2) inter- or intra-agency memoranda or letters (§ 20.62); and (3) personnel, medical, and similar files, the disclosure of which constitutes a clearly unwarranted invasion of personal privacy (§ 20.63).

If written materials contain some information that is disclosable and some information that is not subject to disclosure, the agency can make the materials available to the public after deleting the nondisclosable information (§ 20.22). The process of reviewing the advisory committee materials, determining which information is exempt from disclosure, and redacting the documents to remove the nondisclosable information requires a significant amount of time. For example, in the **Federal Register** of December 22, 1999 (64 FR 71794), FDA announced the availability of a draft guidance document entitled ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000.'' In the draft guidance document, the agency described a 4-week process of reviewing and redacting an advisory committee package submitted by a sponsor of a new drug application and a 3-week process of reviewing and redacting an advisory committee package generated by the Center for Drug Evaluation and Research.

Materials that are otherwise exempt from disclosure under §§ 20.61, 20.62, and 20.63, however, may be disclosed to advisory committee members who are special government employees for use in connection with their work on an advisory committee (§ 20.84). Therefore, the materials provided to advisory committee members need not go through the extensive and time-consuming review and redaction process.

Advisory committees provide meaningful advice to FDA on technical and scientific matters related to the development and evaluation of FDA-regulated products. The value of the advice provided by FDA advisory committees depends, in large part, on the ability of advisory committee members to evaluate diverse, complex, and sometimes contentious scientific issues during the course of a committee meeting. It is crucial that the agency provide advisory committee members background information as soon as practicable after the materials are generated so the members can adequately prepare for the meeting. Because § 14.75(a)(1) provides for the public availability of these materials at the same time as the materials are provided to an advisory committee, and because the advisory committee materials often need to be redacted before being made publicly available, complying with § 14.75(a)(1) would require the agency to wait until the materials are redacted before sending the information to the advisory committees. This, in turn, would result in less time for the committee members to review the materials prior to the committee meeting. This delay would be detrimental to the advisory committee process. Furthermore, simultaneous availability of briefing materials to the advisory committee and to the public is not required under the FACA.

Therefore, the agency is amending § 14.75(a)(1) to state that the written information for consideration by an advisory committee at any meeting is available for public disclosure whenever practicable, before or at the time of the meeting.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. This direct final rule revises § 14.75(a)(1) to reflect current agency policy in conformance with applicable law. The actions taken should be noncontroversial, and the agency does not anticipate receiving any significant adverse comment on this rule.

If FDA does not receive significant adverse comment by March 26, 2001, the agency will publish a document in the **Federal Register** before April 23, 2001, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule before April 23, 2001.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, identical to the direct final rule, that provides a procedural framework within which the

rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to part of this rule and that part may be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. 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.

IV. Analysis of Impacts

FDA has examined the impacts of this direct final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in the other two statutes. This rule is not a significant regulatory action as defined by the Executive order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. The agency has considered the effect that this rule will have on small entities. Because the rule amends only internal agency procedures, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). FDA is not required to prepare a statement of the costs and benefits of this rule because the rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that 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. Accordingly, the agency has concluded that the final rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This direct final rule does not require information collections and, thus, is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

VII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this rule by March 26, 2001. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended to read as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 is revised to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 14.75 is amended by revising paragraph (a)(1) to read as follows:

§ 14.75 Examination of administrative record and other advisory committee records.

(a) * * *

(1) The written information for consideration by the committee at any meeting: Whenever practicable, before or at the time of the meeting.

* * * * *

Dated: December 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–389 Filed 1–5–01; 8:45 am]

BILLING CODE 4160–01–F

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Chapter VIII

[CSOSA–0001]

RIN 3225–ZA00

Organization and Functions

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Final rule.

SUMMARY: The Court Services and Offender Supervision Agency for the District of Columbia (''CSOSA'') is issuing regulations describing its organization and general functions. This description includes information on the District of Columbia Pretrial Services Agency (''PSA''), an independent entity within CSOSA. CSOSA provides supervisory and treatment services to individuals on probation, parole and supervised release for District of Columbia Code violations. CSOSA also