

238–7199 for more information about this AD.

(t) General Electric Company Service Bulletins CF6–80C2 S/B 72–1206, dated December 23, 2005, and CF6–80C2 S/B 72–1207, Revision 01, dated July 05, 2006, pertain to the subject of this AD.

Issued in Burlington, Massachusetts, on February 27, 2007.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–26378; Directorate Identifier 2006–NM–230–AD; Amendment 39–14972; AD 2007–05–11]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–600–2B16 (CL–604) Airplanes and Model CL–600–2B19 (Regional Jet Series 100 & 440) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding two existing airworthiness directives (ADs), that apply to certain Bombardier Model CL–600–2B16 (CL–604) airplanes and Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. These models may be referred to by their marketing designations as RJ100, RJ200, RJ440, CRJ100, CRJ200, CRJ440, and CL–65. One existing AD requires replacing the horizontal stabilizer trim control unit (HSTCU) with a new HSTCU. The other existing AD requires revising the airplane flight manual (AFM) to advise the flightcrew of procedures to follow in the event of stabilizer trim runaway, and in the event of MACH TRIM, STAB TRIM, and horizontal stabilizer trim malfunctions; and revising the AFM to require a review of the location of certain circuit breakers. That AD also requires doing a functional check of the stabilizer trim system and installing circuit breaker identification collars, and provides an optional terminating action. This new AD requires the previously optional terminating action and requires further revisions to the AFM. This AD also requires the removal of certain AFM revisions. This AD results from reports

of trim problems including uncommanded trim, trim in the opposite direction to that selected, loss of trim position indication and, in one case, potential loss of trim disconnect capability. We are issuing this AD to prevent these events, which could result in conditions that vary from reduced controllability of the airplane to loss of control of the airplane.

DATES: This AD becomes effective March 20, 2007.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of March 20, 2007.

On November 14, 2006 (71 FR 63219, October 30, 2006), the Director of the Federal Register approved the incorporation by reference of certain other publications.

On July 30, 1998 (63 FR 34574, June 25, 1998), the Director of the Federal Register approved the incorporation by reference of a certain other publication.

We must receive any comments on this AD by April 4, 2007.

ADDRESSES: Use one of the following addresses to submit comments on this AD.

- *DOT Docket Web site:* Go to <http://dms.dot.gov> and follow the instructions for sending your comments electronically.

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590.

- *Fax:* (202) 493–2251.

- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada, for service information identified in this AD.

You may examine the contents of the AD docket on the Internet at <http://dms.dot.gov>, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2006–26378; the directorate identifier for this docket is 2006–NM–230–AD.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Discussion

On October 13, 2006, the FAA issued a supplemental notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that supersedes AD 2006–22–06, amendment 39–14803 (71 FR 63219, October 30, 2006). The existing AD applies to certain Bombardier Model CL–600–2B16 (CL–604) airplanes and Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. That supplemental NPRM was published in the **Federal Register** on December 28, 2006 (71 FR 78096). That supplemental NPRM proposed to retain the requirements of AD 2006–22–06 and to require the previously optional terminating action (installation of a new horizontal stabilizer trim control unit (HSTCU)). That supplemental NPRM also proposed to require, for certain airplanes, re-inserting the applicable temporary revisions of the Emergency and Abnormal Procedures sections of the airplane flight manual (AFM) under certain conditions.

Actions Since Supplemental NPRM Was Issued

Since we issued that supplemental NPRM, Bombardier has issued new temporary revisions (TRs) to the AFMs as described in a comment submitted by the National Transportation Safety Board (NTSB) (see “Request to Revise AFM Procedures” paragraph below). In the comment, the NTSB presents data to indicate that changes to the AFMs are necessary to address the identified unsafe condition. We have coordinated with Transport Canada Civil Aviation (TCCA) on this issue and concur that changes to the AFMs are necessary. In consideration of these new data, we have determined that the AFMs must be revised to include the new TRs within 14 days after the effective date of this AD.

The FAA finds that, with respect to this additional requirement, since a situation exists that requires immediate adoption of this requirement, notice and time for prior public comment hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days. Therefore, this AD will include the requirements specified in the supplemental NPRM (except the proposed requirement to re-insert TRs to the AFMs), as well as the certain new requirements discussed below. The new requirements include revising the AFMs to include the new TRs. In addition, we

are superseding AD 98–13–24, amendment 39–10615 (63 FR 34574, June 25, 1998). See “Request to Clarify Related AD” paragraph below. This AD restates the requirement of AD 98–13–24 to install a certain HSTCU and specifies that doing the terminating action required by this new AD (installing a new HSTCU) terminates that earlier requirement.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been received.

Request To Revise AFM Procedures

The NTSB requests that we revise the AFM procedures specified in the supplemental NPRM. The NTSB notes that the supplemental NPRM states that AD 2006–22–06 requires and the supplemental NPRM proposes to require:

- Revising the Emergency and Abnormal Procedures sections of the AFM to advise flight crews of procedures to follow in the event of MACH TRIM, STAB TRIM, and horizontal stabilizer trim malfunctions;
- Revising the Normal section of the AFM to require a review of the location of certain circuit breakers and a functional check of the stabilizer trim system [required only by AD 2006–22–06]; and
- Installing circuit breaker identification collars [required only by AD 2006–22–06].

The NTSB summarizes the guidance provided to pilots in the revised

Emergency Procedures section as follows:

- Assume manual control of the control column and override the runaway.
- Press, hold, and release the STAB TRIM disconnect switch.
- If trim motion continues, pull the circuit breakers.

Based on the examination of corroded motherboards and findings during the investigations of the three previous incidents, the NTSB believes that the revised AFM procedures should emphasize that, likely in all cases, an uncommanded movement of the horizontal stabilizer trim is a result of a short-circuit of the first officer’s trim circuits. In addition, because the circuit breakers are accessible only to the first officer in Model CL–600–2B16 airplanes, the NTSB suggests that the Emergency Procedures be revised to indicate that control should be immediately transferred to the captain’s controls to arrest the runaway trim with the captain’s trim switch. Finally, because the only way to arrest a failure mode that occurred only with the trim channels disengaged was to pull the circuit breakers, the NTSB suggests that the procedures should emphasize pulling the circuit breakers if the trim channels are disengaged.

We agree that the AFM should be revised. However, we disagree with the emphasis on trying to disengage the trim on the captain’s side. We consider that it is possible to have contamination on the left- or right-hand side; therefore, both sides should attempt a disengagement.

We agree that control must be transferred to the left-hand side to

facilitate access to the circuit breakers on the right-hand side. However, we consider that the first priority, after regaining control by the pilot flying, is to disconnect the system using the disconnect switches, and that control be passed to the left-hand side subsequent to this step.

We disagree with the suggestion to use the captain’s trim switch to arrest the trim runaway. There have been cases identified of motherboard short circuits where operation of the trim switch would not arrest the runaway. Given the minimal time available to arrest a runaway, priority must be given to the most probable means of arresting the surface motion. These priorities are, first the control column disconnect switches, and second, the circuit breakers.

We also disagree with depending on the Engaged/Disengaged trim channels annunciation to pull the circuit breakers. Instead, the AFM will be changed to remove such reference from the procedure and require that the circuit breakers be pulled in all cases.

We agree to change the AFM procedure to reflect the changes below:

- Control column—Assume manual control and override runaway.
- Both STAB TRIM Disconnect switches—Press, hold and release.
- Control—Transfer to pilot (LH) side.
- STAB CH 1 and CH 2 HSTCU circuit breakers—Open.

The above procedures will be included as memory/immediate action items.

Bombardier has issued and we have reviewed the temporary revisions (TRs) specified in the table below.

TABLE—TRs

For Bombardier Model—	Use—	Dated—	To the—
CL–600–2B16 (CL–604) airplanes	Canadair Challenger TR 604/21–2	January 30, 2007	Canadair Challenger CL–604 AFM, PSP 604–1.
CL–600–2B19 (Regional Jet Series 100 & 440) airplanes.	Canadair Regional Jet TR RJ/152–6.	January 26, 2007	Canadair Regional Jet AFM, CSP A–012.

TR 604/21–2 supersedes Canadair Challenger TR 604/21–1, dated October 3, 2006, and TR RJ/152–6 supersedes Canadair Regional Jet TR RJ/152–5, dated October 3, 2006. Both TRs describe revising the Emergency and Abnormal Procedures sections of the applicable AFM to advise the flightcrew of additional procedures to follow in the event of stabilizer trim runaway and to advise the flightcrew of revised procedures to follow in the event of MACH TRIM, STAB TRIM, and horizontal stabilizer trim malfunctions.

The new TRs must be inserted into the applicable AFM within 14 days after the effective date of this AD. We have determined that this revision is necessary to address uncommanded trim, trim in the opposite direction to that selected, loss of trim position indication and, in one case, potential loss of trim disconnect capability, which could result in conditions that vary from reduced controllability of the airplane to loss of control of the airplane. We have also determined that this revision provides a much more

efficient procedure and a significant improvement for recovery from the stated unsafe condition. We have coordinated with TCCA on this issue. We have added paragraphs (m) and (n) of this AD accordingly to incorporate these AFM revisions.

We have also removed the “Reinsert AFM Revisions” paragraph from this AD (paragraph (n) of the supplemental NPRM). Because this AD requires new AFM revisions, operators do not need to reinsert the old AFM revisions that may

have been removed in accordance with AD 2006-22-06.

Request To Clarify the Unsafe Condition

The NTSB requests that we clarify the unsafe condition to state accurately the potential severity of uncommanded motion of the horizontal stabilizer trim on the affected airplanes. The NTSB states that the severity can range from major to catastrophic, based on the assessment of airplane performance under various runaway stabilizer trim conditions and the circumstances of the three recent reported incidents.

The NTSB states that pilots from Bombardier Flight Test, TCCA, the FAA, and the NTSB have performed a comprehensive assessment of Model CL-600-2B16 and CL-600-2B19 airplane performance under various runaway stabilizer trim conditions using full flight simulators, desktop simulations, and test airplanes. The NTSB notes that the consensus from those efforts is that, depending on the nature of the runaway condition, the risk assessment can range from major to catastrophic.

The NTSB also notes that the variables that affect the operational safety risk are the direction of the trim runaway, the ability to disconnect or override the trim, and whether the runaway is intermittent or constant. The NTSB states that the worst-case scenario (resulting in complete loss of airplane control) would be a constant trim runaway in the nose-up direction without the ability to disconnect or override the trim, and at the other end of the hazard assessment is an intermittent runaway trim in the nose-down direction with the ability to disconnect and override the trim. The NTSB has determined that the intermittent runaway trim scenario, if managed properly with no other extenuating circumstances, could be relatively benign; however, the NTSB explains that functional capabilities would still be reduced while crew workload and distress would increase, potentially affecting the crew's performance of other tasks. The NTSB concludes that this condition could end catastrophically if managed poorly or if other factors, such as weather, traffic, or other system failures, complicate operations.

We agree to clarify the unsafe condition specified in this AD for the reasons provided by the NTSB. We have revised the unsafe condition in the Summary and paragraph (d) of this AD to read:

This AD results from reports of trim problems including uncommanded trim, trim

in the opposite direction to that selected, loss of trim position indication and, in one case, potential loss of trim disconnect capability. We are issuing this AD to prevent these events, which could result in conditions that vary from reduced controllability of the airplane to loss of control of the airplane.

Request To Clarify Related AD

Comair also requests that we clarify whether this supplemental NPRM supersedes AD 98-13-24. Comair asks if the following requirement for certain airplanes in AD 98-13-24 also applies to the supplemental NPRM: "replace the HSTCU with a new HSTCU having part number 601R92301-9." Comair points out that AD 98-13-24 does not acknowledge replacing with a higher dash number (the supplemental NPRM specifies, and this new AD requires, replacement with a HSTCU having part number 601R92301-15 or higher dash number).

We acknowledge the need to clarify how AD 98-13-24 relates to this AD. AD 98-13-24, which applies to Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes, serial numbers 7003 through 7112 inclusive, requires the installation of the HSTCU, part number (P/N) 601R92301-9, within 18 months after the effective date of that AD as a terminating action for other actions specified in that AD. Since AD 98-13-24 became effective on July 30, 1998, all Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes in the United States are required to be in compliance. If any airplane is imported, it must be in compliance with all applicable ADs, including AD 98-13-24.

As this new AD requires the replacement of a part already cited in AD 98-13-24, we determined that this could lead to confusion regarding applicability and result in unnecessary record keeping. This new AD requires that the HSTCU be replaced with a higher part number (HSTCU P/N 601R92301-15 or higher dash number).

Therefore, we have determined that this AD should supersede AD 98-13-24 as well as AD 2006-22-06 (the supplemental NPRM proposed to supersede AD 2006-22-06). We have revised paragraph (b) of this AD to read:

"This AD supersedes AD 98-13-24 and AD 2006-22-06."

We have also restated the requirements of paragraph (b) of AD 98-13-24 as paragraph (f) of this AD. We have revised the remaining paragraph identifiers accordingly.

All of the airplanes on the U.S. Register affected by AD 98-13-24 are already in compliance with the actions required by AD 98-13-24; therefore, the

requirements and costs to U.S. operators described in the supplemental NPRM will not change. We have determined that providing notice and opportunity for public comment on superseding AD 98-13-24 is unnecessary before this AD is issued.

Requests To Extend Compliance Time

The Regional Airline Association (RAA), on behalf of its members Air Wisconsin, Mesa Airlines, PSA Airlines, and Comair, requests that we extend the 9-month compliance time for the terminating action to read, "within 12 months after the effective date of this AD." RAA notes that TCCA mandated a 12-month retrofit from the TCCA airworthiness directive's published date in October but the TCCA's airworthiness directive is applicable only to the relatively small fleet of Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes that operate in Canada. RAA recommends that we consult with Sagem (the parts manufacturer) to finalize our decision on a suitable compliance period and to consider that the airworthiness concern has never occurred within the regional fleet, and interim operational measures are currently in effect.

Mesa Airlines states there have been no documented failures on the Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes and that the newly imposed circuit breaker identification and AFM revision will preclude an unlikely failure from becoming an incident. Mesa Airlines recommends that 6 months be added to the compliance time for these airplanes.

Air Wisconsin concurs with the comments from Mesa Airlines. Air Wisconsin states that it doubts that the parts schedule will be able to be maintained and notes that an optimistic parts schedule issued by Bombardier will have the operator installing parts into October 2007. PSA Airlines agrees with Mesa Airlines and Air Wisconsin that the 9-month compliance time is not realistic.

Comair requests that we contact Bombardier and Sagem to determine if the schedule is realistic and will not place an undue burden on the operators. Comair notes that it has received units that failed prior to first flight and that these occurrences are not allotted for in the delivery schedule. Comair also states that it is nine units behind in receiving upgraded units based on the proposed shipping schedule.

We disagree, because in developing an appropriate compliance time for this action, we considered the urgency associated with the subject unsafe condition, the availability of required

parts, and the practical aspect of accomplishing the required installation within a period of time that corresponds to the normal scheduled maintenance for most affected operators. According to Bombardier, enough required parts will be available to modify the U.S. fleet within the proposed compliance time. However, according to the provisions of paragraph (q) of this AD, we may approve requests to adjust the compliance time if the request includes data that prove that the new compliance time would provide an acceptable level of safety. We have not revised this AD in this regard.

Request To Reduce Compliance Time

The NTSB requests that we reduce the 9-month compliance time to do the terminating action specified in supplemental NPRM. The NTSB is concerned that this compliance time may not sufficiently protect the fleet of affected airplanes from this hazardous condition. The NTSB notes that although the three previous in-flight incidents all involved Model CL-600-2B16 airplanes, a review of FAA service difficulty reports (SDR) for Bombardier CRJ 100/200 airplanes revealed more than 500 anomalies with stabilizer trim in the last six years, including at least eight reports of uncommanded movement of the horizontal stabilizer that were reported in that time.

The NTSB received statistics from the HSTCU manufacturer (Sagem Avionics, Inc.) that showed an average return rate of approximately 425 HSTCUs per year with approximately 10 percent of HSTCU motherboards found to have some level of corrosion. The NTSB states that none of these boards had corrosion on the specific pins that control the captain's trim commands, which is significant because in the event of a trim runaway, a command from the captain's trim switch could override an uncommanded trim movement caused by the first officer's circuits.

The NTSB states that various short-circuit scenarios were then extensively tested and that for every scenario tested (except for one), the captain's trim switch could be used to arrest or override a runaway trim. The NTSB notes that analysis of this condition to date suggests that any of the motherboards could be affected by corrosion and that corrosion can usually only be detected by disassembly of the HSTCU. The NTSB points out that HSTCUs with extensively corroded motherboards have passed built-in-test-equipment tests, as well as the manufacturer's acceptance test procedure, which could result in faulty HSTCUs not being removed from

service. The NTSB adds that the boards examined were not cleaned sufficiently following the manufacturing process, which, in conjunction with sufficient moisture by condensation, could result in corrosion and pin-to-pin shorting and lead to trim runaway or several less significant anomalies. The NTSB states that the sampling of corroded boards would suggest that perhaps 50 airplanes are currently operating with contaminated motherboards, which, when coupled with sufficient moisture, will cause malfunctions. Data evaluated so far by NTSB investigators suggests that corrosion-induced runaway events occur randomly, independent of the age of the affected motherboard.

The NTSB notes that a continuing airworthiness assessment performed by Bombardier estimated the probability of the corrosion failure mode causing uncommanded continuous trim movement at full speed of the horizontal stabilizer without disconnect capability to be 7.6×10^{-8} per flight hour. However, the NTSB believes that, regardless of trim runaway direction or disconnect capability, any uncommanded runaway event presents the flight crew with a hazardous situation that, depending on other operational factors, may result in an accident. Accordingly, using the three in-flight incidents, the eight events from the SDR database, and the combined fleet history of 13 million flight hours, the NTSB believes a more conservative estimate of incident probability is 8.5×10^{-7} per flight hour. The NTSB believes that this estimate may be optimistic considering it is likely that more of the SDRs were actually trim runaway events that were not correctly diagnosed. The NTSB states that data provided by Bombardier indicates that the average combined fleet utilization is 2.8 million flight hours per year. The NTSB considers that the fleet may accumulate this number of flight hours over the AD compliance interval and therefore as many as two uncommanded runaway events could be expected to occur before the proposed AD is fully complied with. Even with this more conservative estimate, the NTSB notes that the three in-flight events have occurred very recently in the fleet's 13-million-flight-hour history, which suggests that some of the factors driving uncommanded trim events may not have been present or consistent over the entire history. Therefore, the NTSB concludes that the true probability of future events, in particular over the compliance period, is difficult to estimate accurately.

The NTSB states that it is aware that Bombardier has been working with the HSTCU manufacturer to accelerate

hardware production in regards to this AD. However, the NTSB is concerned that the FAA's proposed compliance time is formulated based on the quoted production rate and that uncertainty about the safety risk warrants priority consideration. Therefore, the NTSB strongly encourages the FAA to consider a shorter compliance time that provides reasonable assurance that the corrective action will be fully implemented without risking additional runaway events.

We disagree with the request to reduce the compliance time because in developing an appropriate compliance time for this action, we considered the urgency associated with the subject unsafe condition, the availability of required parts, and the practical aspect of accomplishing the required installation within a period of time that corresponds to the normal scheduled maintenance for most affected operators. The FAA's and TCCA's harmonized position is that the stated compliance time of 9 months strikes the correct balance of risk mitigation. Bombardier has committed to the delivery of modified HSTCUs to meet this schedule. Any shortening of the compliance time may result in fleet groundings since there will not be sufficient modified HSTCUs available. However, as stated previously, we have revised the AFM procedures to provide a much more efficient procedure and a significant improvement for recovery from the stated unsafe condition.

Request To Remove First Flight of Day Functional Test

Air Wisconsin requests that we remove the requirement for the airplane's first flight of the day functional test specified in the supplemental NPRM. The commenter states that the requirement was removed from the AFM at Revision 55 in July 2001 and therefore, there was no requirement to do this action for over 5 years until it was again required by AD 2006-22-06. The commenter notes that the terminating action in the supplemental NPRM allows operators to remove the temporary revision to abnormal procedures and the circuit breaker identification collars. The commenter concludes that the requirement for a daily functional test should be removed because the supplemental NPRM does not contain justification for retaining the test.

We partially agree. We intended in AD 2006-22-06 for the first flight of the day check of the pitch trim disconnect switch to give crews a way to know daily that the disconnect switch is available and functional, because use of

the pitch trim disconnect can significantly mitigate the severity of uncommanded trim movement. Installing the modified HSTCU required by this AD is terminating action for certain actions in AD 2006-22-06 and mitigates the higher risk of uncommanded movement. Therefore, the functional test is not necessary because the replacement has already mitigated the risks.

We have revised this AD to remove the requirement for this functional test in the Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes. Therefore, we have revised paragraph (o)(1) of this AD to require the removal of the AFM revisions required by paragraphs (j) and (k) of this AD after the installation required by paragraph (o) of this AD is done. Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes have had a history of pitch trim disconnect switch failures, which cause loss of both Channel 1 and 2 with resultant loss of pitch trim. We have been advised that exercising the switch increases wear and induces additional failures. That is the reason why this check was removed from the Canadair Regional Jet AFM at an earlier date. The Stab Trim System Reliability including switch reliability is covered in FAA Safety Recommendation 04.093. We have been strongly recommending a new switch, or a life limit on the existing switch, as well as other system improvements. Since Model CL-600-2B16 (CL-604) airplanes incur much less usage than Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes, switch wear is not considered a driver and hence the Stab Trim Check was recommended for the Model CL-600-2B16 (CL-604) airplanes.

Also, since the Model CL-600-2B16 (CL-604) fleet already contains this functional test in its airplane flight manual, it will be recommended but not mandated that Model CL-604 crews continue to perform this functional test. Therefore, we have added a note after paragraph (o)(1) of this AD stating:

It is recommended for Model CL-600-2B16 (CL-604) operators that the functional check of the stabilizer trim system on the aircraft's first flight of the day continue to be performed in accordance with the Normal Procedures Section of the Canadair Challenger CL-604 AFM.

Request for Alternative Method of Compliance

Comair requests that we provide an alternative method of compliance for the actions specified in paragraph (l) of the supplemental NPRM. Comair notes that paragraph (l) specifies to do the installation, for certain airplanes, in

accordance with Bombardier Service Bulletin 601R-27-147, dated September 28, 2006, and paragraph B.(2) of the Accomplishment Instructions of the service bulletin specifies to do Sagem Service Bulletin HSTCU-27-011. Comair states that operators cannot "do" the Sagem service bulletin because units must be returned to Sagem for the upgrade. Comair states that this makes the installation a replacement of the HSTCU with the upgraded HSTCU. Comair states that the airplane maintenance manual (AMM) procedure for installation of the HSTCU, task 27-41-01-400-801, requires the same functional check and operational check called out in the referenced service bulletin. We infer that Comair requests that we refer to the AMM procedure as an alternative method of compliance.

We disagree. Operators are not required to do the Sagem service bulletin. Paragraph (o) of this AD (paragraph (l) in the supplemental NPRM) requires installing the HSTCU P/N 601R92301-15 (Vendor P/N 7060-10) or higher dash number in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601R-27-147 (for Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes). Although paragraph B.2 of the Accomplishment Instructions in Bombardier Service Bulletin 601R-27-147 states "Do the Avionics service bulletin HSTCU-27-011," this AD requires only that the HSTCU be installed and does not require operators to perform the actual modifications.

In addition, we do not agree with referring to the AMM reference in this AD as a method of compliance for installing the modified HSTCU. The installation must be done in accordance with Bombardier Service Bulletin 601R-27-147. Bombardier Service Bulletin 601R-27-147 refers to the procedures in AMM 27-41-01-400-801 for the installation. Doing the procedures in any revision of the AMM is acceptable for complying with the installation requirements of this AD. In addition, according to the provisions of paragraph (q) of this AD, we may approve requests for alternative compliance methods if the request includes data that prove that the actions would provide an acceptable level of safety. We have not revised this AD in this regard.

Request To Revise Cost Paragraph

RAA also request that we revise the cost of the installation. RAA states that one of its members pointed out that the cost to upgrade to a unit "- 10" is \$15,000.

We do not agree to revise the cost of an upgrade to \$15,000. Operators should

note that when we calculate estimated costs, we do not consider job set up, close up, etc., to be part of the work hour calculation. Also, although the calculations in the supplemental NPRM used a figure of 11 work hours for installation, in fact, the only work hour numbers that should be used for the estimate should be 1 work hour for "Procedure" as specified in Bombardier Service Bulletin 601R-27-147. For the parts costs, we referred to the "Material Information" section in Sagem Service Bulletin HSTCU-27-011, dated September 22, 2006, which specifies a range from \$0 to upgrade Sagem P/N 7060-9A that is under warranty up to \$3,995 to upgrade a Sagem P/N 7060-8 or older version that is not under warranty. We have not revised this AD in this regard because the cost of compliance paragraph is not restated in this type of rulemaking action.

Request To Disallow Removal of Circuit Breaker Collars

The Air Line Pilots Association (ALPA) requests that we disallow the removal of the circuit breaker identification collars that is allowed in paragraph (l) of the supplemental NPRM (paragraph (o) of this AD). ALPA states that procedures in place at several carriers rely on the crew's ability to readily identify the circuit breakers, and the existing circuit breaker collars facilitate that procedure. ALPA expects that even with the improvement represented by the supplemental NPRM, the procedures will continue to remain available to crews, so leaving the collars in place represents a safety benefit.

We disagree because the wording in the AD allows for the removal of the collars but does not mandate the action. The circuit breaker collars were considered an interim action for quick identification in the case of runaway trim with an associated pitch trim system disconnect failure. The installation of the modified HSTCUs is considered terminating action for this risk. Therefore, we are not imposing the additional requirement for operators to maintain the circuit breaker collars after the installation has already mitigated the risks. We have not revised this AD in this regard.

Conclusion

We have carefully reviewed the available data, including the comments that have been received, and determined that air safety and the public interest require adopting the AD with the changes described previously.

FAA's Determination and Requirements of This AD

These airplanes are manufactured in Canada and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, TCCA has kept the FAA informed of the situation described above. We have examined TCCA's findings, evaluated all pertinent information, and determined that AD action is necessary for airplanes of this type design that are certificated for operation in the United States.

Therefore, we are issuing this AD to supersede AD 2006-22-06 and AD 98-13-24 and to continue to require the actions specified in those ADs. This AD also requires doing the terminating action (installation of a new HSTCU), and revising the Emergency and Abnormal Procedures sections of the AFM, which replace the existing revisions. This AD also requires the removal of certain AFM revisions.

Change to Supplemental NPRM

As a result of superseding AD 98-13-24 and adding an action due to the new service information, we have changed certain paragraph identifiers and added others.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD; therefore, providing notice and opportunity for public comment before the AD is issued is impracticable, and good cause exists to make this AD effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any relevant written data, views, or arguments regarding this AD. Send your comments to an address listed in the **ADDRESSES** section. Include "Docket No. FAA-2006-26378; Directorate Identifier 2006-NM-230-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD that might suggest a need to modify it.

We will post all comments we receive, without change, to <http://dms.dot.gov>, including any personal information you provide. We will also post a report summarizing each

substantive verbal contact with FAA personnel concerning this AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78), or you can visit <http://dms.dot.gov>.

Examining the Docket

You may examine the AD docket on the Internet at <http://dms.dot.gov>, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647-5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. 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.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that the 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. 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 AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39-10615 (63 FR 34574, June 25, 1998) and amendment 39-14803 (71 FR 63219, October 30, 2006) and by adding the following new airworthiness directive (AD):

2007-05-11 Bombardier, Inc. (Formerly Canadair): Docket No. FAA 2006-26378; Directorate Identifier 2006-NM-230-AD; Amendment 39-14972.

Effective Date

(a) This AD becomes effective March 20, 2007.

Affected ADs

(b) This AD supersedes AD 98-13-24 and AD 2006-22-06.

Applicability

(c) This AD applies to Bombardier Model CL-600-2B16 (CL-604) airplanes, serial numbers 5301 through 5665 inclusive; and Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes, serial numbers 7003 through 7990 inclusive and 8000 through 8066 inclusive; certificated in any category.

Note 1: The Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes may be referred to by their marketing designations as RJ100, RJ200, RJ440, CRJ100, CRJ200, CRJ440, and CL-65.

Unsafe Condition

(d) This AD results from reports of trim problems including uncommanded trim, trim

in the opposite direction to that selected, loss of trim position indication and, in one case, potential loss of trim disconnect capability. We are issuing this AD to prevent these events, which could result in conditions that vary from reduced controllability of the airplane to loss of control of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Restatement of Certain Requirements of AD 98-13-24

Replacement of Horizontal Stabilizer Trim Control Unit (HSTCU)

(f) For Model CL-600-2B19 (Regional Jet Series 100) airplanes, serial numbers 7003 through 7112 inclusive: Within 18 months after July 30, 1998 (the effective date of AD 98-13-24), replace the HSTCU with a new HSTCU having part number 601R92301-9,

and reactivate the mach trim switch/light (if deactivated), in accordance with Bombardier Service Bulletin S.B. 601R-27-053, Revision B, dated February 21, 1997. Doing paragraph (o) of this AD terminates the requirements of this paragraph.

Note 2: Accomplishment of paragraph (f) of this AD, prior to July 30, 1998, in accordance with Bombardier Service Bulletin S.B. 601R-27-053, dated May 27, 1996; or Revision A, dated August 26, 1996; is considered acceptable for compliance with the applicable actions specified in paragraph (f) of this AD.

Restatement of Certain Requirements of AD 2006-22-06

Airplane Flight Manual (AFM) Revisions

(g) Within 14 days after November 14, 2006 (the effective date of AD 2006-22-06), make the applicable AFM revisions specified in paragraph (g)(1) or (g)(2) of this AD by incorporating the applicable Canadair

(Bombardier) temporary revisions (TRs) identified in Table 1 of this AD into the applicable AFM. Doing the revision specified in paragraph (m) of this AD terminates the requirements of this paragraph for those airplanes only.

(1) For Model CL-600-2B16 (CL-604) airplanes: Revise the Emergency and Abnormal Procedures sections of the AFM to advise the flightcrew of additional procedures to follow in the event of stabilizer trim runaway and to advise the flightcrew of revised procedures to follow in the event of MACH TRIM, STAB TRIM, and horizontal stabilizer trim malfunctions.

(2) For Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes: Revise the Emergency and Abnormal Procedures sections of the AFM to advise the flightcrew of revised procedures to follow in the event of stabilizer trim runaway and in the event of MACH TRIM, STAB TRIM, and horizontal stabilizer trim malfunctions.

TABLE 1—TRS

For Bombardier Model—	Use—	Dated—	To the—
CL-600-2B16 (CL-604) airplanes	Canadair Challenger TR 604/21-1	October 3, 2006	Canadair Challenger CL-604 AFM, PSP 604-1.
CL-600-2B19 (Regional Jet Series 100 & 440) airplanes.	Canadair Regional Jet TR RJ/152-5.	October 3, 2006	Canadair Regional Jet AFM, CSP A-012.

(h) When the applicable TR specified in paragraph (g) of this AD has been included in the general revisions of the applicable AFM, those general revisions may be inserted into the AFM and the applicable TR may be removed, provided the relevant information in the general revisions is identical to that in the TR.

Installation of Circuit Breaker Identification Collars

(i) Within 14 days after November 14, 2006, install circuit breaker identification collars in accordance with Bombardier

Modification Summary Package IS601R27410051, Revision C, dated September 29, 2006 (for Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes); or the Accomplishment Instructions of Bombardier Alert Service Bulletin A604-27-029, dated September 28, 2006 (for Model CL-600-2B16 (CL-604) airplanes); as applicable.

Additional AFM Revision

(j) For Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes: Within 14 days after November 14, 2006, revise the Normal

section of the Canadair Regional Jet AFM, CSP A-012, to include the statement specified in Figure 1 of this AD. This may be done by inserting a copy of Figure 1 of this AD into the AFM.

“Prior to the flightcrew’s first flight of the day, do the following actions:

1. Review the location of the STAB CH1 HSTCU and STAB CH2 HSTCU circuit breakers.
2. Complete a functional check of the stabilizer trim system as detailed below.

Control Wheel Stab Trim Disconnect Check

Control Wheel Stab Trim Disconnect switches Check

- Make sure STAB TRIM caution message is out.
- Activate the pilot’s Control Wheel Stab Trim Disconnect switch and make sure the STAB TRIM caution message comes on.
- Engage the STAB TRIM switches and make sure the STAB TRIM caution message is out.
- Activate the co-pilot’s Control Wheel Stab Trim Disconnect switch and make sure the STAB TRIM caution message comes on.
- Engage the STAB TRIM and MACH TRIM switches and make sure the STAB TRIM and MACH TRIM caution messages are out.”

NOTE:

During ground testing only, do not activate the Control Wheel Stab Trim Disconnect switch if the horizontal stabilizer trim is in motion.

Figure 1

Note 3: When a statement identical to that in paragraph (j) of this AD has been included in the general revisions of the applicable AFM, those general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

(k) For Model CL-600-2B16 (CL-604) airplanes: Within 14 days after November 14, 2006, revise the Normal section of the Canadair Challenger CL-604 AFM, PSP 604-1, to include the following statement. This

may be done by inserting a copy of this AD into the AFM.

“Prior to the flightcrew’s first flight of the day, do the following actions:

1. Review the location of the STAB CH1 HSTCU and STAB CH2 HSTCU circuit breakers.
2. Check the stabilizer trim system as detailed in CL-604 AFM ‘Normal Procedures’ section titled ‘Flight Controls Trim Systems, Before Flight—First Flight of the Day.’”

Note 4: When a statement identical to that in paragraph (k) of this AD has been included in the general revisions of the applicable AFM, those general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

Previous Actions Accomplished According to Modification Summary Package

(l) Actions accomplished before November 14, 2006, in accordance with Bombardier Modification Summary Package

IS601R27410051, Revision A, dated September 18, 2006; or Revision B, dated September 27, 2006; are considered acceptable for compliance with the action specified in paragraph (i) of this AD, provided that the circuit breaker collars meet the color requirements of Bombardier Modification Summary Package IS601R27410051, Revision C, dated September 29, 2006.

New Requirements of This AD

New Revised AFM Revisions

(m) Within 14 days after the effective date of this AD, make the applicable AFM

revisions specified in paragraph (m)(1) or (m)(2) of this AD by incorporating the applicable Canadair (Bombardier) TRs identified in Table 2 of this AD into the applicable AFM, and after doing the revision, remove the applicable AFM revision required by paragraph (g) of this AD from the applicable AFM. Doing the applicable revision specified in this paragraph terminates the requirements of paragraph (g) for that airplane.

(1) For Model CL-600-2B16 (CL-604) airplanes: Revise the Emergency and Abnormal Procedures sections of the AFM to advise the flightcrew of procedures to follow

in the event of stabilizer trim runaway and in the event of MACH TRIM, STAB TRIM, and horizontal stabilizer trim malfunctions.

(2) For Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes: Revise the Emergency and Abnormal Procedures sections of the AFM to advise the flightcrew of revised procedures to follow in the event of stabilizer trim runaway and in the event of MACH TRIM, STAB TRIM, and horizontal stabilizer trim malfunctions.

TABLE 2.—REVISED TRS

For Bombardier Model—	Use—	Dated—	To the—
CL-600-2B16 (CL-604) airplanes	Canadair Challenger TR 604/21-2	January 30, 2007	Canadair Challenger CL-604 AFM, PSP 604-1.
CL-600-2B19 (Regional Jet Series 100 & 440) airplanes.	Canadair Regional Jet TR RJ/152-6.	January 26, 2007	Canadair Regional Jet AFM, CSP A-012.

(n) When the applicable TR specified in paragraph (m) of this AD has been included in the general revisions of the applicable AFM, those general revisions may be inserted into the AFM and the applicable TR may be removed.

Terminating Action—Installation of New, Improved Part

(o) Within 9 months after the effective date of this AD, install HSTCU, part number (P/N) 601R92301-15 (vendor P/N 7060-10) or higher dash number, in accordance with the Accomplishment Instructions of Bombardier Alert Service Bulletin A604-27-029, dated September 28, 2006 (for Model CL-600-2B16 (CL-604) airplanes); or Bombardier Service Bulletin 601R-27-147, dated September 28, 2006 (for Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes); as applicable. Doing this installation terminates the requirements of paragraph (f) of this AD. After doing this installation, the circuit breaker identification collars required by paragraph (i) of this AD may be removed. After doing this installation, the requirements specified in paragraphs (o)(1) and (o)(2) of this AD must be followed.

(1) Within 14 days after doing the installation or within 14 days after the

effective date of this AD, whichever occurs later, the AFM revisions required by paragraphs (j) and (k) of this AD must be removed from the AFM.

Note 5: It is recommended for Model CL-600-2B16 (CL-604) operators that the functional check of the stabilizer trim system on the aircraft's first flight of the day continue to be performed in accordance with the Normal Procedures Section of the Canadair Challenger CL-604 AFM.

(2) After doing the installation, the AFM revisions required by paragraph (g) of this AD may be removed from the applicable AFM, but only if the removal of the AFM revisions was done before the effective date of this AD.

Note 6: Bombardier Service Bulletin 601R-27-147, dated September 28, 2006, refers to SageM Service Bulletin HSTCU-27-011, dated September 22, 2006, as an additional source of service information for accomplishment of the installation.

Service Bulletin Exception

(p) Although Bombardier Alert Service Bulletin A604-27-029, dated September 28, 2006, specifies to return certain parts to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(q)(1) The Manager, New York Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(r) Canadian airworthiness directives CF-2006-20R1, dated October 4, 2006, and CF-2006-21R1, dated October 3, 2006, also address the subject of this AD.

Material Incorporated by Reference

(s) You must use Bombardier Modification Summary Package IS601R27410051, Revision C, dated September 29, 2006; the service bulletins listed in Table 3 of this AD; and the temporary revisions listed in Table 4 of this AD; as applicable, to perform the actions that are required by this AD, unless the AD specifies otherwise.

TABLE 3.—SERVICE BULLETINS INCORPORATED BY REFERENCE

Service bulletin	Revision level	Date
Bombardier Alert Service Bulletin A604-27-029	Original	September 28, 2006.
Bombardier Service Bulletin S.B. 601R-27-053	B	February 21, 1997.
Bombardier Service Bulletin 601R-27-147	Original	September 28, 2006.

TABLE 4.—ALL TEMPORARY REVISIONS INCORPORATED BY REFERENCE

Temporary revision—	Dated—	To the—
Canadair Challenger Temporary Revision 604/21-1	October 3, 2006	Canadair Challenger CL-604 Airplane Flight Manual, PSP 604-1.
Canadair Challenger Temporary Revision 604/21-2	January 30, 2007 ...	Canadair Challenger CL-604 Airplane Flight Manual, PSP 604-1.

TABLE 4.—ALL TEMPORARY REVISIONS INCORPORATED BY REFERENCE—Continued

Temporary revision—	Dated—	To the—
Canadair Regional Jet Temporary Revision RJ/152-5	October 3, 2006	Canadair Regional Jet Airplane Flight Manual, CSP A-012.
Canadair Regional Jet Temporary Revision RJ/152-6	January 26, 2007 ...	Canadair Regional Jet Airplane Flight Manual, CSP A-012.

(1) The Director of the Federal Register approved the incorporation by reference of the temporary revisions listed in Table 5 of

this AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

TABLE 5.—NEW TEMPORARY REVISIONS INCORPORATED BY REFERENCE

Temporary revision—	Dated—	To the—
Canadair Challenger Temporary Revision 604/21-2	January 30, 2007 ...	Canadair Challenger CL-604 Airplane Flight Manual, PSP 604-1.
Canadair Regional Jet Temporary Revision RJ/152-6	January 26, 2007 ...	Canadair Regional Jet Airplane Flight Manual, CSP A-012.

(2) On November 14, 2006 (71 FR 63219, October 30, 2006), the Director of the Federal Register approved the incorporation by reference of Bombardier Alert Service Bulletin A604-27-029, dated September 28,

2006; Bombardier Service Bulletin 601R-27-147, dated September 28, 2006; Bombardier Modification Summary Package IS601R27410051, Revision C, dated September 29, 2006; and the temporary

revisions listed in Table 6 of this AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

TABLE 6.—PREVIOUS TEMPORARY REVISIONS INCORPORATED BY REFERENCE

Temporary revision—	Dated—	To the—
Canadair Challenger Temporary Revision 604/21-1	October 3, 2006	Canadair Challenger CL-604 Airplane Flight Manual, PSP 604-1.
Canadair Regional Jet Temporary Revision RJ/152-5	October 3, 2006	Canadair Regional Jet Airplane Flight Manual, CSP A-012.

(3) On July 30, 1998 (63 FR 34574, June 25, 1998), the Director of the Federal Register approved the incorporation by reference of Bombardier Service Bulletin S.B. 601R-27-053, Revision B, dated February 21, 1997; in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(4) Contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada, for a copy of this service information. You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on February 21, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7-3661 Filed 3-2-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committee: Change of Name and Function

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and function of the Advisory Committee for Pharmaceutical Science. This action is being taken to reflect changes made to the charter for this advisory committee.

DATES: This rule is effective March 5, 2007.

FOR FURTHER INFORMATION CONTACT:

Theresa Green, Committee Management Officer (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Advisory Committee for Pharmaceutical Science, which was established on January 22, 1990, has been changed. The

name Advisory Committee for Pharmaceutical Science and Clinical Pharmacology more accurately describes the subject areas for which the committee is responsible. The committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

FDA is revising § 14.100(c)(16) (21 CFR 14.100(c)(16)) to reflect these changes. In this document, FDA is hereby formally changing the name and the function of the committee by revising § 14.100(c)(16). Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(B)