

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

SOCATA: Docket No. FAA–2011–1139; Directorate Identifier 2011–CE–021–AD.

Comments Due Date

(a) We must receive comments by December 5, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to SOCATA Model TBM 700 airplanes, serial numbers (SN) 1 through 572, 574, and 576, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 27: Flight Controls.

Reason

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

A TBM 700 operator reported a case of inverted installation of aileron control cables in the wing. The shortest cable was found installed instead of the longest one on wing tip side, with left hand (LH) threaded end in upper section. This wrong installation could have been caused by mistaken maintenance data.

This condition, if not detected and corrected, could lead to restricted movement of the aileron, resulting in reduced control of the aeroplane, particularly when operating under adverse flight conditions on landing and during avoidance manoeuvres.

For the reasons described above, this AD requires an inspection to verify the correct installation of the aileron control cables and, in case of discrepancies, proper re-installation of the cables in accordance with the approved design configuration.

Even with potentially reduced aileron deflection, Socata's analysis shows that the airplane is still capable of achieving its published cross wind landing limits.

Actions and Compliance

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

(1) Within 12 months after the effective date of this AD or within 100 hours time-in-service (TIS) after the effective date of this AD, whichever occurs first, inspect the aileron control cables in left and right wings for proper installation following the accomplishment instructions of DAHER–

SOCATA Mandatory Service Bulletin SB 70–191–27, dated April 2011.

(2) If during the inspection required by paragraph (f)(1) of this AD you find the cables are improperly installed, before further flight, remove the cables and correctly re-install the cables following the accomplishment instructions of DAHER–SOCATA Mandatory Service Bulletin SB 70–191–27, dated April 2011.

(3) After the effective date of this AD, after each removal of the aileron control cables, you must re-install using the maintenance manual temporary revisions below:

(i) *For S/N 1 through 433:* SOCATA TBM 700 Model Maintenance Manual Temporary Revision No. TR040.27, dated April 2011.

(ii) *For S/N 434 through 572, 574 and 576:* SOCATA TBM 850 Maintenance Manual Temporary Revision No. TR015.27, dated April 2011.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: The compliance time of the MCAI is 12 months after the effective day of the AD. This differs from the service bulletin of 12 months or 100 hours TIS, whichever occurs first. To assure that the unsafe condition is addressed on all airplanes in a timely manner, the FAA is using the compliance time from the service bulletin.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4119; *fax:* (816) 329–4090; *e-mail:* albert.mercado@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions,

completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2011–0101, dated May 25, 2011; DAHER–SOCATA Mandatory Service Bulletin SB 70–191–27, dated April 2011; SOCATA TBM 700 Model Maintenance Manual Temporary Revision No. TR040.27, dated April 2011; and SOCATA TBM 850 Maintenance Manual Temporary Revision No. TR015.27, dated April 2011, for related information. For service information related to this AD, contact SOCATA—Direction des Services—65921 Tarbes Cedex 9—France; telephone +33 (0) 62 41 7300, fax +33 (0) 62 41 76 54, or for North America: SOCATA NORTH AMERICA, 7501 South Airport Road, North Perry Airport (HWO), Pembroke Pines, Florida 33023; *telephone:* (954) 893–1400; *fax:* (954) 964–4141; *e-mail:* mysocata@socata.daher.com; *Internet:* <http://mysocata.com>. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on October 14, 2011.

John Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–27264 Filed 10–20–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1155; Directorate Identifier 2011–CE–032–AD]

RIN 2120–AA64

Airworthiness Directives; Schempp-Hirth Flugzeugbau GmbH Gliders

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Schempp-Hirth Flugzeugbau GmbH Model Discus 2cT gliders. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify

and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

It has been reported that small cracks on engine pylons, in the area of the lower engine support, were not detected through the "standard" inspection required by the daily inspection instructions. The cracks were discovered only after having significantly grown.

This condition, if not detected and corrected, could lead to an engine pylon failure and consequent damage to the aeroplane or injury to people on the ground.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by December 5, 2011.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact: Schempp-Hirth Flugzeugbau GmbH, Krehenstrasse 25, D-73230 Kirchheim/Teck, Germany; *phone:* +49 7021 7298-0; *fax:* +49 7021 7298-199; *Internet:* <http://www.schempp-hirth.com>; *e-mail:* info@schempp-hirth.com.

You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329-4165; *fax:* (816) 329-4090; *e-mail:* jim.rutherford@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2011-1155; Directorate Identifier 2011-CE-032-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD No.: 2011-0146, dated August 3, 2011 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

It has been reported that small cracks on engine pylons, in the area of the lower engine support, were not detected through the "standard" inspection required by the daily inspection instructions. The cracks were discovered only after having significantly grown.

This condition, if not detected and corrected, could lead to an engine pylon failure and consequent damage to the aeroplane or injury to people on the ground.

For the reasons described above, this AD requires to replace the daily inspections pages of the Aircraft Flight Manual (AFM) that are describing the engine pylon inspection instructions, to inspect the affected engine pylon area in accordance with those instructions, and the replacement with a newly designed engine pylon in case of findings.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Schempp-Hirth Flugzeugbau GmbH has issued Schempp-Hirth Flugzeugbau GmbH Technical Note No. 863-14,

dated July 18, 2006; and Schempp-Hirth Flugzeugbau GmbH Technical Note No. 863-20, Revision 1, dated July 27, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We have proposed additional actions in this AD from those in the MCAI to provide for additional inspections. We believe that in addition to the daily pilot inspections of the engine pylon, that an initial and annual repetitive inspection be accomplished by a properly certificated aircraft mechanic. We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

We estimate that this proposed AD will affect 3 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$255, or \$85 per product.

In addition, we estimate that any necessary follow-on actions would take about 8 work-hours and require parts costing \$1,697, for a cost of \$2,377 per product. We have no way of

determining the number of products that may need these actions.

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 determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 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. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Schempp-Hirth Flugzeugbau: Docket No. FAA-2011-1155; Directorate Identifier 2011-CE-032-AD.

Comments Due Date

(a) We must receive comments by December 5, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Schempp-Hirth Flugzeugbau Discus 2cT gliders, serial numbers 1 through 35, certificated in any category, except those on which an engine pylon, part number (P/N) M03RT841, is installed.

Subject

(d) Air Transport Association of America (ATA) Code 54: Nacelles/Pylons.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states: It has been reported that small cracks on engine pylons, in the area of the lower engine support, were not detected through the "standard" inspection required by the daily inspection instructions. The cracks were discovered only after having significantly grown.

This condition, if not detected and corrected, could lead to an engine pylon failure and consequent damage to the aeroplane or injury to people on the ground.

For the reasons described above, this AD requires to replace the daily inspections pages of the Aircraft Flight Manual (AFM) that are describing the engine pylon inspection instructions, to inspect the affected engine pylon area in accordance with those instructions, and the replacement with a newly designed engine pylon in case of findings.

Actions and Compliance

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

(1) Within 30 days after the effective date of this AD, replace the daily inspection pages of the airplane flight manual following Schempp-Hirth Flugzeugbau GmbH Technical Note No. 863-20 Revision 1, dated July 27, 2011. The actions required by this paragraph may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9 (a)(1)-(4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439. All other actions in this AD must be done by a properly certificated aircraft mechanic.

(2) Before further flight after doing the action in paragraph (f)(1) of this AD and repetitively thereafter at intervals not to exceed every 12 months, inspect the engine pylon for damage or cracks, following the daily inspection instructions as amended by Schempp-Hirth Flugzeugbau GmbH Technical Note No. 863-20 Revision 1, dated July 27, 2011.

(3) If during the daily inspections in the instructions amended by Schempp-Hirth Flugzeugbau GmbH Technical Note No. 863-20 Revision 1, dated July 27, 2011 in paragraph (f)(1) of this AD or the inspections required in paragraph (f)(2) of this AD, any damage or crack is found on the engine pylon, before further flight, replace the engine pylon with an engine pylon part number M03RT841 following Schempp-Hirth Flugzeugbau GmbH Technical Note No. 863-14, dated July 18, 2006.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: In addition to the daily pilot inspections of the engine pylon required by the foreign authority, the FAA also requires an initial and annual repetitive inspection by a properly certificated aircraft mechanic.

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4165; fax: (816) 329-4090; e-mail: jim.rutherford@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments

concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, *Attn:* Information Collection Clearance Officer, AES-200.

Related Information

(h) Refer to MCAI EASA AD No.: 2011-0146, dated August 3, 2011; Schempp-Hirth Flugzeugbau GmbH Technical Note No. 863-14, dated July 18, 2006; and Schempp-Hirth Flugzeugbau GmbH Technical Note No. 864-20 Revision 1, dated July 27, 2011, for related information. For service information related to this AD, contact Schempp-Hirth Flugzeugbau GmbH, Krehenstrasse 25, D-73230 Kirchheim/Teck, Germany; *phone:* +49 7021 7298-0; fax +49 7021 7298-199; *Internet:* <http://www.schempp-hirth.com>; *e-mail:* info@schempp-hirth.com. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Issued in Kansas City, Missouri, on October 17, 2011.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011-27267 Filed 10-20-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-354]

Schedules of Controlled Substances: Placement of Ezogabine Into Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes placing the substance ezogabine, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule V of the Controlled Substances Act (CSA). This proposed action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking.

DATES: DEA will permit interested persons to file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted and written comments must be postmarked on or before November 21, 2011. Commenters should be aware that the electronic Federal Docket

Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),”¹ may file a request for hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and 1316.47. Requests for hearing, notices of appearance, and waivers of participation must be received on or before November 21, 2011.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-354” on all electronic and written correspondence. DEA encourages all comments be submitted electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document and supplemental information to this proposed rule are also available at the <http://www.regulations.gov> Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to <http://www.regulations.gov> will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/OD, 8701 Morrisette Drive, Springfield, VA 22152. All requests for hearing must be sent to Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Rhea D. Moore, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 307-7165.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA’s public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the

public docket, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA’s public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency’s public docket file in person by appointment, please see the “For Further Information” paragraph.

Request for Hearing, Notice of Appearance at or Waiver of Participation in Hearing

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (5 U.S.C. 556 and 557) and 21 CFR 1308.41. Pursuant to 21 CFR 1308.44(a)–(c), requests for hearing, notices of appearance, and waivers of participation may be submitted only by interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).” Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b) and 1316.47 or 1316.48, as applicable. A request or notice should state, with particularity, the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c), including a written statement regarding the interested

¹ 21 CFR 1300.01.