Reserve Bank or state regulatory authority; and

(iii) Is not subject to any written agreement, cease and desist order, capital directive, or prompt corrective action directive issued by the Board or a Federal Reserve Bank.

By order of the Board of Governors of the Federal Reserve System, May 25, 1994.

William W. Wiles,

Secretary of the Board.

[FR Doc. 94–13253 Filed 6–2–94; 8:45 am]

BILLING CODE 6210–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM–96; Special Conditions No. 25–ANM–85]

Special Conditions: Modified AMD/BA Falcon 50 Series Airplanes, High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for AMD/BA Falcon 50 series airplanes modified by Duncan Aviation, Inc., of Lincoln, Nebraska. These airplanes are equipped with digital electronic flight instrument systems (EFIS) that perform critical functions. The applicable regulations do not contain adequate or appropriate safety standards for the protection of the EFIS from the effects of high-intensity radiated fields (HIRF). These special conditions provide the additional safety standards that the Administrator considers necessary to ensure that the critical functions performed by these systems are maintained when the airplane is exposed to HIRF.

DATES: The effective date of these special conditions is May 24, 1994. Comments must be received on or before July 18, 1994.

ADDRESSES: Comments on these final special conditions; request for comments, may be mailed in duplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, Attn.: Rules Docket (ANM–7), Docket No. NM–96, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; or delivered in duplicate to the Office of the Assistant Chief Counsel at the above address. Comments must be marked "Docket No. NM–96." Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Mark Quam, FAA, Standardization Branch, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (206) 227–2145.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that good cause exists for making these special conditions effective upon issuance; however, interested persons are invited to submit such written data, views, or arguments as they may desire. Communications should identify the regulatory docket and special conditions number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. These special conditions may be changed in light of the comments received. All comments submitted will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this request must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. NM–96." The postcard will be date stamped and returned to the commenter.

Background

On April 15, 1994, Duncan Aviation, Inc., of Lincoln, Nebraska, applied for a supplemental type certificate to modify the AMD/BA Falcon 50 series airplanes. The AMD/BA Falcon 50 is a business jet with three aft-mounted turbojet engines. The airplane can carry two pilots and 8 to 19 passengers, depending on the exit and interior configuration, and is capable of operating to an altitude of 45,000 feet. The proposed modification incorporates the installation of digital avionics consisting of an electronic flight instrument system (EFIS) that is potentially vulnerable to high-intensity radiated fields (HIRF) external to the airplane.

Supplemental Type Certification Basis

Under the provisions of § 21.101 of the Federal Aviation Regulations (FAR), Duncan Aviation, Inc., must show that the altered AMD/BA Falcon 50 series airplanes continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A46EU, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis."

The regulations incorporated by reference in Type Certificate No. A46EU include the following for the AMD/BA Falcon 50 series: § 21.29 of part 21, and 14 CFR part 25, dated February 1, 1965, as amended by Amendments 25–1 through 25–34. In addition the following regulations apply to the EFIS installation: §§ 25.1303(b) and 25.1322, as amended through Amendment 25–38; and §§ 25.1309, 25.1321(a), (b), (d), and (e), 25.1331, 25.1333, and 25.1335, as amended by Amendment 25–41. These special conditions will form an additional part of the supplemental type certification basis.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25, as amended) do not contain adequate or appropriate safety standards for the AMD/BA Falcon 50 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR after public notice, as required by §§ 11.28 and 11.29, and become part of the type certification basis in accordance with § 21.101(b)(2).

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from high-intensity radiated fields (HIRF). Increased power levels from ground-based radio transmitters, and the growing use of sensitive electrical and electronic systems to command and control airplanes, have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the modified AMD/BA Falcon 50 series airplanes that would require that the EFIS be designed and installed to

preclude component damage and interruption of function due to the effects of HIRF.

High-Intensity Radiated Fields (HIRF)

When the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems, such as the EFIS, to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraphs 1 or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–100 KHz	50	50
100 KHz–500 KHz	60	60
500 KHz–2000 KHz	70	70
2 MHz–30 MHz	200	200
30 MHz–70 MHz	30	30
70 MHz–100 MHz	30	30
100 MHz–200 MHz	150	33
200 MHz–400 MHz	70	70
400 MHz–700 MHz	4,020	935
700 MHz–1000 MHz	1,700	170
1 GHz–2 GHz	5,000	990
2 GHz–4 GHz	6,680	840
4 GHz–6 GHz	6,850	310
6 GHz–8 GHz	3,600	670
8 GHz–12 GHz	3,500	1,270
12 GHz–18 GHz	3,500	360
18 GHz–40 GHz	2,100	750

The envelope given in paragraph 2 above is a revision to the envelope used in previously issued special conditions in other certification projects. It is based on new data and SAE AE4R subcommittee recommendations. This revised envelope includes data from Western Europe and the U.S.

As discussed above, these special conditions are applicable to the AMD/BA Falcon 50 series airplanes, modified by Duncan Aviation. Should Duncan Aviation apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A46EU to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well, under the provisions of § 21.101(a)(1).

Conclusion

This action affects only certain unusual or novel design features on the AMD/BA Falcon 50 series airplanes. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of the special conditions for these airplanes has been subjected to the notice and comment procedure in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. For this reason, and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions immediately. Therefore, these special conditions are being made effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. app. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2), 42 U.S.C. 1857f–10, 4321 et seq.; E.O. 11514; and 49 U.S.C. 106(g).

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the supplemental type certification basis for the modified AMD/BA Falcon 50 series airplanes:

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high-intensity radiated fields external to the airplane.

2. The following definition applies with respect to this special condition: *Critical Function.* Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane. Issued in Renton, Washington, on May 24, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

[FR Doc. 94–13521 Filed 6–2–94; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 39

[Docket No. 94–NM–08–AD; Amendment 39–8930; AD 94–12–03]

Airworthiness Directives; Airbus Model A320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Airbus Model A320 series airplanes, that currently requires modification of the belly fairing structure. This amendment revises the compliance time for accomplishment of the modification. This amendment is prompted by the fact that the compliance time of the existing rule would have allowed operators of low-cycle airplanes to accomplish the modification at a time considerably later than that intended. The requirements of this amendment are intended to ensure that the structural integrity of the belly fairing structure is maintained.

DATES: Effective July 5, 1994.

The incorporation by reference of certain publications as listed in the regulations was approved previously by the Director of the Federal Register as of January 10, 1994 (58 FR 64875, December 10, 1993).

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Stephen Slotte, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2797; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations by superseding AD 93–24–11, Amendment 39–8760 (58 FR 64875, December 10, 1993), which is applicable to certain Airbus Model A320 series airplanes, was published in the **Federal Register** on February 2, 1994 (59 FR 4869). The action proposed to supersede AD 93–24–11 to continue to require modification of the belly fairing structure, but to revise the compliance time for accomplishing the modification. That action was prompted by the fact that the compliance time currently specified in paragraph (a) of AD 93–24–11 could allow certain operators to accomplish the modification at a time considerably later than that intended. The proposal proposed to revise the compliance time to "prior to the accumulation of 12,000 total landings on the airplane, or within 300 days after the effective date of the final rule, whichever occurs later." This compliance time will ensure that the structural integrity of the belly fairing structure is maintained in a timely manner.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the three comments received.

All commenters support the proposed rule.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that 20 airplanes of U.S. registry were affected by AD 93–24–11, and will continue to be affected by this supersedure of that AD. It will take approximately 288 work hours per airplane to accomplish the actions currently required by AD 93–24–11, and that the average labor rate is $55 per work hour. Required parts will cost approximately $1,045 per airplane. Based on these figures, the current cost impact of AD 93–24–11 on U.S. operators is estimated to be $337,700, or $16, 885 per airplane.

The total cost impact figure discussed above is presented as if no operator has yet accomplished any of the requirements of AD 93–24–11 (or this supersedure of that AD). There are no foreseeable additional costs that will be imposed by this supersedure of AD 93–24–11.

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

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8760 (58 FR 64875, December 10, 1993), and by adding a new airworthiness directive (AD), amendment 39–8930, to read as follows:

94–12–03 Airbus Industrie: Amendment 39–8930. Docket 94–NM–08–AD. Supersedes AD 93–24–11, Amendment 39–8760.

Applicability: Model A320 series airplanes, MSN 003 through 092 inclusive, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced structural integrity of the belly fairing structure, accomplish the following:

(a) Prior to the accumulation of 12,000 total landings on the airplane, or within 300 days after January 10, 1994 (the effective date of AD 93–24–11, Amendment 39–8760), whichever occurs later: Modify the belly fairing structure in accordance with Airbus Industrie Service Bulletin A320–53–1014, dated June 25, 1992, or Revision 1, dated May 26, 1993.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

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

(d) The modification shall be done in accordance with Airbus Industrie Service Bulletin A320–53–1014, dated June 25, 1992, or Airbus Industrie Service Bulletin A320–53–1014, Revision 1, dated May 26, 1993. The incorporation by reference of these documents was approved previously by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 as of January 10, 1994 (59 FR 64875, December 10, 1993). Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on July 5, 1994.

Issued in Renton, Washington, on May 26, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–13372 Filed 6–2–94; 8:45 am]

BILLING CODE 4910–13–U

RAILROAD RETIREMENT BOARD

20 CFR Part 200

[RIN 3220–AB05]

Availability of Information to the Public

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (Board) amends its regulations establishing fees to be assessed in connection with the search for records and provision of documents by the Board. The regulations provide that the fees will be based on the salaries of the employees who ordinarily perform the searches.

EFFECTIVE DATE: June 3, 1994.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Michael C. Litt, Bureau of Law, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, (312) 751–4929, TDD (312) 751–4701.

SUPPLEMENTARY INFORMATION: Title 5 U.S.C. 552(a) requires the promulgation of a regulation specifying the schedule of fees applicable to the processing of requests for information. These fees are to provide for the recovery of the direct costs of search, duplication, and review. The fees previously provided for in § 200.4(g)(1) no longer reflect the actual costs of processing requests for information and do not include fees for specific methods of transmittal of documents. The Board is amending its regulation to update the fees by establishing criteria for determining fees so that the fees will automatically change with changes in Federal salaries. In addition, the Board is increasing the fees found in section 200.4(g) and is adding a new paragraph to provide a charge for transmittal of documents by other than regular post.

On January 14, 1994, the Board published this rule as a proposed rule (59 FR 2317), inviting comments on or before February 14, 1994. No comments were received. The final rule differs from the proposed rule in that we have deleted specific salary amounts to be assessed for search and review and substituted therefor language that will allow these fees to rise with salary rate increases. Also the maximum computer search charge has been reduced from that in the proposed rule in accordance with more current information.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action for purposes of Executive Order 12866. Therefore, no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR Part 200

Railroad employees, Railroad retirement, Railroad unemployment insurance.

For the reasons set out in the preamble, title 20, chapter II, part 200 of the Code of Federal Regulations is amended as follows:

PART 200—GENERAL ADMINISTRATION

1. The authority citation for part 200 continues to read as follows:

Authority: 45 U.S.C. 231f(b)(5) and 45 U.S.C. 362; § 200.4 also issued under 5 U.S.C. 552; § 200.5 also issued under 5 U.S.C. 552; § 200.6 also issued under 5 U.S.C. 552b; § 200.7 also issued under 31 U.S.C. 3717.

2. Section 200.4 is amended by revising paragraph (g)(1) to read as follows:

§ 200.4 Availability of information to public.

* * * * *

(g) * * *

(1) *Fee schedule.* To the extent that the following are chargeable, they are chargeable according to the following schedule:

(i) The charge for making a manual search for records shall be the salary rate, including benefits, for a GS–7, step 5 Federal employee;

(ii) The charge for reviewing documents to determine whether any portion of any located document is permitted to be withheld shall be the salary rate, including benefits, for a GS–13, step 5 Federal employee;

(iii) The charge for making photocopies of any size document shall be $.10 per copy per page;

(iv) The charge for computer-generated listings or labels shall include the direct cost to the RRB of analysis and programming, where required, plus the cost of computer operations to produce the listing or labels. The maximum computer search charge shall be $2,250.00 per hour ($37.50 per minute). Search time shall not include the time expended in analysis or programming where these operations are required.

(v) There shall be no charge for transmitting documents by regular post. The charge for all other methods of transmitting documents shall be the actual cost of transmittal.

* * * * *

Dated: May 27, 1994.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 94–13522 Filed 6–2–94; 8:45 am]

BILLING CODE 7905–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 90C–0453]

Listing of Color Additives Exempt From Certification; Synthetic Iron Oxide; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of April 7, 1994, of the final rule that appeared in the **Federal Register** of March 7, 1994 (59 FR 10578), that amended the color additive regulations to provide for the safe use of synthetic iron oxide in human food, specifically sausage casings.

DATES: Effective date confirmed: April 7, 1994.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS–207), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3107.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 7, 1994 (59 FR 10578), FDA amended 21 CFR 73.200 of the color additive regulations to provide for the safe use of synthetic iron oxide as a color additive in human food, specifically sausage casings.

FDA gave interested persons until April 6, 1994, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA has concluded that the final rule published in the **Federal Register** of March 7, 1994, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), and redelegated to the Director, Center for Food Safety and Applied Nutrition, notice is given that no objections or requests for a hearing were filed in response to the March 7, 1994, final rule. Accordingly, the amendments promulgated thereby became effective April 7, 1994.

Dated: May 25, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–13587 Filed 6–2–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 346

[Docket No. 80N–0050]

RIN 0905–AA06

Anorectal Drug Products for Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule with opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the monograph for over-the-counter (OTC) anorectal drug products. This amendment updates the monograph to incorporate a United States Pharmacopeia (U.S.P.) name change for an active ingredient included in the monograph. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: This final rule is effective January 1, 1995; written comments by August 17, 1994.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 3, 1990 (55 FR 31776), FDA issued a final monograph for OTC anorectal drug products (21 CFR part 346). That monograph included "Hamamelis water, 'The National Formulary XI' " as an active ingredient in § 346.18(b). "Hamamelis water" was also cited in §§ 346.50 (b)(2)(vi) and (d)(8). Because Hamamelis water had last been included in an official compendium in The National Formulary XI (Ref. 1), it was named in this manner in § 346.18(b).

In 1993 (Refs. 2 and 3), Hamamelis water was proposed for inclusion in U.S.P. XXIII, which becomes official on January 1, 1995. The proposed official name was subsequently changed from "Hamamelis water" to "Witch Hazel" (Ref. 3). To be consistent with the change in compendial status and to give manufacturers advance notice of the need for revised labeling, the agency is changing the name of the ingredient "Hamamelis water" to "witch hazel" in the final monograph for OTC anorectal drug products. These changes will occur in § 346.18(b) in the ingredient listing and in § 346.50 in the introductory text of paragraphs (b)(2)(vi) and (d)(8). These changes will become effective on January 1, 1995.

The amendment will require revised product labeling to substitute witch hazel for hamamelis water. This labeling revision represents a minor clarifying change that does not change the substance of the labeling requirements contained in the final regulations. Because sections 502 (e)(1) and (e)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 (e)(1) and (e)(3)) require the established name of a drug to be used, any "witch hazel" drug product initially introduced or initially delivered for introduction into interstate commerce after January 1, 1995, will need to bear the new established name "witch hazel."

As noted previously, these changes make the final monograph for OTC anorectal drug products consistent with a change being implemented in the official compendium (U.S.P.). Because the name change follows from a U.S.P. change, the Commissioner has determined that notice and comment are unnecessary (5 U.S.C. 553(b); 21 CFR 10.40(e)(1)). Therefore, publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). This final rule shall become effective on January 1, 1995.

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In this final rule, the labeling change could be implemented by manufacturers at very little cost at the next printing of labels. There are only a few manufacturers of products containing this ingredient. Accordingly, the agency certifies that the final 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.

The agency invites public comment regarding any economic impact that this rulemaking would have on the labeling of OTC drug products. Types of impact may include, but are not limited to, costs associated with relabeling. Comments regarding the impact of this final rule on OTC drug products should be accompanied by appropriate documentation. The agency will consider any comments to determine whether the regulation should subsequently be modified.

Interested persons may, on or before August 17, 1994, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Written comments on the agency's economic impact determination may be submitted on or before August 17, 1994. Three copies of all 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(c)(6) 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.

References

(1) "The National Formulary," 11th ed., Mack Publishing Co., Easton, PA, p. 158, 1960.

(2) "Pharmacopeial Forum," The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 5266–5268, May and June 1993.

(3) "Pharmacopeial Forum," The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 6399–6401, November and December 1993.

List of Subjects in 21 CFR Part 346

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner