

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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would revise Colored Federal Airways in Alaska.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, “Environmental Impacts: Policies and Procedures,” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and

effective September 15, 2009, is to be amended as follows:

Paragraph 6009(a) Green Federal Airways.
* * * * *

G–16 [Revised]

From Point Lay, AK, NDB; Wainwright Village, AK, NDB; Browerville, AK, NDB; Nuiqsut Village, AK, NDB; to Put River, AK, NDB.

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Paragraph 6009(d) Blue Federal Airways.
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B–26 [Revised]

From Chena, AK, NDB, to Yukon River, AK, NDB.

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Issued in Washington, DC, September 28, 2009.

Edith V. Parish,

Manager, Airspace and Rules Group.

[FR Doc. E9–23884 Filed 10–2–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 4

[Docket No. FDA–2009–N–0435]

Current Good Manufacturing Practice Requirements for Combination Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of September 23, 2009 (74 FR 48423). The document proposed to codify the current good manufacturing practice requirements applicable to combination products. The document published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. E9–22850, appearing on page 48423, in the **Federal Register** of Wednesday, September 23, 2009, the following corrections are made:

1. On page 48423, in the third column, in the Docket No. heading, “[Docket No. FDA–2008–D–0409]” is corrected to read “[Docket No. FDA–2009–N–0435]”.

2. On page 48423, in the third column, in the **ADDRESSES** section, beginning in the second line, “[Docket No. FDA–2008–D–0409] (formerly Docket No. 2004D–0431)” is corrected to read “[Docket No. FDA–2009–N–0435]”.

Dated: September 28, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23899 Filed 10–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AD75

Special Regulations, Areas of the National Park System, Grand Teton National Park

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service (NPS) proposes to designate certain multi-use pathways in Grand Teton National Park as routes for bicycle use; NPS regulations require issuance of a special regulation to designate routes for bicycle use when it will be off park roads and outside developed areas. Several segments of multi-use pathways have been constructed, or are planned for construction, and are located parallel to and generally within about 50 feet of existing park roads. Moving bicycle traffic off the lanes of motor vehicle travel will reduce real and perceived safety hazards, which will enhance opportunities for non-motorized enjoyment of the park, and encourage the use of alternate transportation by park employees and visitors. In addition, the NPS is proposing revisions to its regulations regarding fishing and boating in certain park waters of Grand Teton National Park to reflect current operating practices and management objectives.

DATES: Comments must be received by December 4, 2009.

ADDRESSES: You may submit your comments, identified by Regulatory Information Number 1024–AD75 (RIN), by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Grand Teton National Park, P.O. Drawer 170, Moose, WY 83012.
- *Hand Deliver to:* Superintendent’s Office, Moose, Wyoming.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Gary Pollock, Management Assistant, Grand Teton National Park, 307-739-3428 or at the address listed in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION:

Background

Grand Teton National Park is located in northwest Wyoming, and encompasses approximately 310,000 acres. Located just to the south of Yellowstone National Park, Grand Teton is at the heart of the Greater Yellowstone Ecosystem, and includes the iconic mountains of the Teton Range, the broad valley of Jackson Hole, numerous lakes, and a 40-mile segment of the Snake River. The park was originally established in 1929, but at that time included only the mountains and several of the lakes at their base. In 1943, Jackson Hole National Monument was established by presidential proclamation, including much of the valley to the east of the mountains. In 1950, Congress combined the 1929 park and the national monument into the present-day national park, ending the long and controversial period that led up to the park's establishment.

The park supports diverse and abundant populations of wildlife, and is world renowned for its opportunities to view elk, moose, bison, pronghorn, grizzly and black bears, grey wolves, and coyotes. Other species, such as trumpeter swans, bald eagles, and many species of waterfowl and small mammals are also abundant.

Visitors to Grand Teton National Park typically participate in several types of activities, including scenic touring, viewing wildlife, hiking, mountain climbing, fly fishing, float trips, bicycling, and other forms of recreation consistent with enjoyment of the park's resources. The park includes several major developed areas, five campgrounds, almost 200 miles of

hiking trails, 140 miles of paved roads, and 70 miles of unpaved roads. Visitation to the park has remained relatively constant over the last decade at approximately 2.5 million recreational visitors, mostly occurring between the months of May and September.

In April 2000, Grand Teton National Park undertook a transportation study to provide basic information regarding transportation issues in the park. The study served as a foundation for the next step in the process, which included the development of a transportation plan that was initiated in September 2001. The *Transportation Plan/Final Environmental Impact Statement* (FEIS) was released in September 2006. A *Record of Decision* (ROD) selecting Alternative 3a was signed on March 12, 2007, and a notice of the decision was published in the **Federal Register** on April 24, 2007 (72 FR 20365). A full description of the alternatives that were considered, the environmental impacts associated with the project, and public involvement can be found online at <http://www.nps.gov/grte/parkmgmt/tranplan.htm>.

Although the planning effort and ROD addressed a variety of transportation-related issues, a major focus was on the development of a system of multi-use pathways to improve opportunities for non-motorized activities within the park. Bicycling has become increasingly popular in the park, and many visitors and others who commented during the planning process expressed concerns over the risks that are present when bicycles and motor vehicles share the road. Commentors often noted that this was particularly true for families with young children or visitors who are not experienced bicyclists.

Among the issues that were raised during the planning process were the potential effects of the pathway system on the park's wildlife. Although wildlife is abundant and often visible from park roads, it is well documented that animals respond differently to pedestrians and bicyclists than they do to the mere presence of motor vehicles. The potential for reducing the effectiveness of habitat and displacing wildlife from areas located near the pathways was a significant concern for many individuals and organizations that commented during the planning process. Furthermore, in light of the park's abundant wildlife, concerns were raised regarding the potential for surprise encounters between bicyclists and large animals, including grizzly bears.

The ROD sets forth the park's decision for the development of an extended

system of multi-use pathways within the park. The system will include 39 miles of pathways between the south park boundary and Colter Bay via the Teton Park Road, as well as a 3-mile segment along the Moose-Wilson Road between the Granite Canyon Entrance and the Laurance S. Rockefeller Preserve. In general, pathways will be constructed within 50 feet of the road, except that the 16-mile segments between North Jenny Lake Junction and Colter Bay and along the Moose-Wilson Road will be constructed in very close proximity to the roads, generally within the existing engineered and previously disturbed road corridors.

The preferred alternative in the final plan/EIS, and subsequently adopted in the ROD, addressed the concerns regarding wildlife through a combination of research and monitoring, construction phasing, and the requirement that certain portions of the pathway system would be constructed within the existing road corridors. Specifically, the ROD includes a significant emphasis on wildlife research and monitoring to provide detailed understanding of the effects of pathway development. Monitoring and research activities were begun in 2007 to provide a pre-construction baseline, and will continue through at least 2009. The phased approach to construction of the pathway system will allow information obtained from the research and monitoring program to be integrated into the design and operation of each subsequent pathway segment. Finally, for those portions of the pathway system between North Jenny Lake Junction and Colter Bay, and along the Moose-Wilson Road, the pathways will be located within the engineered corridor in which the existing roadways are located. Since the road corridors are less frequently used by wildlife than the adjacent habitat, and have generally clear lines of sight, the chances for surprise encounters between bicyclists and wildlife would be reduced to essentially the same level that exists on the road shoulder.

The first phase of pathways was constructed during the summer and fall of 2008. These segments extend from the Dornan's inholding near park headquarters in Moose along the Teton Park Road to the South Jenny Lake area, a distance of approximately 8 miles. Additional segments may be constructed as funds become available.

This proposed rule complies with 36 CFR 4.30, which requires the NPS to designate bicycle routes outside of developed areas through promulgation of a special regulation. That regulation further specifies that such routes may be

designated only upon “* * * a written determination that such use is consistent with the protection of a park area’s natural, scenic and aesthetic values, safety considerations and management objectives and will not disturb wildlife or park resources.” The Superintendent has made such a determination and found that the designation of the pathway segment between Moose and South Jenny Lake as a route for bicycle use is consistent with the requirements of 36 CFR 4.30.

The proposed rule would also make several changes to the special regulations for Grand Teton National Park to reflect current operating practices or changes to the park’s land status. The proposed rule would close Phelps Lake to the operation of motor boats, consistent with all other backcountry lakes in the park. This change is prompted by the change in land status for the area surrounding the southern half of the lake. Prior to November 2007, these lands were a private inholding within the park known as the JY Ranch, owned by Laurance S. Rockefeller and, subsequent to his death, by his estate. The property functioned as a family guest ranch and retreat for the Rockefeller family since the 1930s, where guests typically engaged in activities such as hiking, horseback riding, and boating on Phelps Lake. The ranch included a boathouse on the lakeshore where motorboats were kept during the summer. The park’s special regulations authorized the use of motorboats on Phelps Lake, thereby allowing the JY Ranch to continue a use that had existed prior to the park’s establishment. No other motorboat use occurred on the lake since it was inaccessible to park visitors except on foot or horseback.

Before his death, Mr. Rockefeller made a decision to donate the property to the United States for inclusion within Grand Teton National Park. In accordance with Mr. Rockefeller’s wishes, all buildings, roads, and other development were removed by his estate, and a system of trails to allow visitors to enjoy the area was constructed. The property was acquired by the United States in November 2007. The proposed rule would remove the now unnecessary provision to allow motorboat use on Phelps Lake.

The proposed rule would remove the provision in § 7.22(b) that allows authorized marine bait dealers, all of which are park concessioners, to keep certain species of fish taken from Jackson Lake and sell them as bait. The NPS determined that provision to be unnecessary and inconsistent with NPS Management Policies 2006 and the

practice was discontinued several years ago.

Section-by-Section Analysis

§ 7.22(b) Fishing

The proposed rule would eliminate the provision in paragraph (3) that authorizes marine bait dealers at Jackson Lake to take certain species of fish taken from Jackson Lake or waters that flow into Jackson Lake and sell those fish as bait.

§ 7.22(e) Vessels

The proposed rule would eliminate the reference to Phelps Lake in paragraph (1), thus prohibiting the use of motorboats on that body of water. Motorboats would continue to be allowed on Jackson and Jenny lakes.

§ 7.22(h) Where may I ride a bicycle in Grand Teton National Park?

The proposed rule adds a new paragraph to the special regulations for Grand Teton National Park, designating two segments of existing multi-use pathways as routes for bicycle use. The general regulations for bicycle use in the National Park System require that such designation be accomplished by the promulgation of a special regulation. The proposed rule would designate the segments that were completed in 2008.

Compliance With Other Laws

Regulatory Planning and Review (Executive Order 12866)

This document is not a significant rule and is not subject to review by the Office of Management and Budget under Executive Order 12866.

(1) This rule will not have an effect of \$100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. This is based on information contained in the report titled “Cost-Benefit and Regulatory Flexibility Analyses: Proposed Regulations Designating Pathways for Multi-Use in Grand Teton National Park,” which is available for public review at <http://www.regulations.gov>.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. Implementing actions under this rule will not interfere with plans by other agencies or local government plans, policies, or controls since this is an agency specific change.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights

or obligations of their recipients. It only affects the use of bicycles and motorboats within Grand Teton National Park. No grants or other forms of monetary supplement are involved.

(4) This rule does not raise novel legal or policy issues. This rule simply implements the Servicewide bicycle regulation regarding bicycle routes in Grand Teton National Park.

Regulatory Flexibility Act

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This certification is based on information contained in the report titled, “Cost-Benefit and Regulatory Flexibility Analyses: Proposed Regulations Designating Pathways for Multi-Use in Grand Teton National Park,” which is available for public review at <http://www.regulations.gov>.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of \$100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

This determination is based on information from “Cost-Benefit and Regulatory Flexibility Analyses: Proposed Regulations Designating Pathways for Multi-Use in Grand Teton National Park” which can be found at <http://www.regulations.gov>. This action does not involve additional construction, fees, or other measures that would increase costs to visitors, businesses, communities, or the Park. Therefore, this action will not impose any costs.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. It addresses public use of national park

lands, and imposes no requirements on other agencies or governments.

Takings (E.O. 12630)

Under the criteria in Executive Order 12630, this rule does not have significant takings implications. A takings implication assessment is not required.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This proposed rule only affects use of NPS administered lands and waters. It has no outside effects on other areas.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

- (a) Does not unduly burden the justice system;
- (b) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and
- (c) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission under the Paperwork Reduction Act (PRA) is not required.

National Environmental Policy Act

In accordance with the National Environmental Policy Act, the National Park Service prepared an Environmental Impact Statement and Record of Decision for the uses contemplated in the proposed rule. A copy of the documents can be obtained by contacting the Superintendent, Grand Teton National Park, P.O. Drawer 170, Moose, Wyoming 83012. The documents are also available online at <http://www.nps.gov/grte/parkmgmt/tranplan.htm>.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government to Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM 2:

We have evaluated the potential effects on federally recognized Indian tribes and have determined that there are no potential effects. Representatives of the eleven tribes affiliated with Grand

Teton National Park were consulted during the preparation of the Environmental Impact Statement for the project.

Clarity of Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use clear language rather than jargon;
- (d) Be divided into short sections and sentences; and
- (e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Drafting Information: The primary authors of this regulation were Gary Pollock, Management Assistant, Grand Teton National Park, Michael Tiernan, Office of the Solicitor, U.S. Department of the Interior and Philip A. Selleck, Chief, Regulations and Special Park Uses, National Park Service.

Public Participation

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

List of Subjects in 36 CFR Part 7

National parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR Part 7 as set forth below:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

1. The authority citation for Part 7 is revised to read as follows:

Authority: 16 U.S.C. 1, 3, 9a, 462(k); Sec. 7.96 also issued under D.C. Code 10–137(2001) and D.C. Code 50–2201 (2001).

2. Amend § 7.22 to revise paragraphs (b)(3) and (e)(1) and add a new paragraph (h) to read as follows:

§ 7.22 Grand Teton National Park.

* * * * *

(b) * * *

(3) *Bait:* The use or possession of fish eggs or fish for bait is prohibited, except it shall be permissible to possess or use the following dead, non-game fish for bait on or along the shores of Jackson Lake: Redside shiner, speckled dace, longnose dace, piute sculpin, mottled sculpin, Utah chub, Utah sucker, bluehead sucker, and mountain sucker.

* * * * *

(e) *Vessels.* (1) Motorboats are prohibited on all park waters except Jackson Lake and Jenny Lake. On Jenny Lake, motorboats are restricted to motors not in excess of 7½ horsepower. Additionally, on Jenny Lake, an authorized boating concessioner may operate motorboats under conditions specified by the Superintendent.

* * * * *

(h) *Where may I ride a bicycle in Grand Teton National Park?* (1) You may ride a bicycle on park roads, in parking areas, and upon designated routes established within the park in accordance with § 4.30(a) of this chapter. The following routes are designated for bicycle use:

(i) The paved multi-use pathway between Dornan's and the Teton Park Road.

(ii) The paved multi-use pathway alongside the Teton Park Road between Dornan's Junction and the South Jenny Lake developed area.

(2) The Superintendent may open or close designated bicycle routes, or portions thereof, for bicycle use after taking into consideration the location of wildlife, the amount of snow cover or other environmental conditions, public safety, and other factors, pursuant to the criteria and procedures of §§ 1.5 and 1.7 of this chapter.

Dated: July 20, 2009.

Will Shafroth,

Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E9–23946 Filed 10–2–09; 8:45 am]

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