

the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: November 27, 2017.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2017-25873 Filed 11-30-17; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 29, 2017.

A. Federal Reserve Bank of St. Louis
(David L. Hubbard, Senior Manager)

P.O. Box 442, St. Louis, Missouri 63166-2034. Comments can also be sent electronically to

Comments.applications@stls.frb.org;

1. *McGehee Bank Employee Stock Ownership Plan, McGehee, Arkansas*; to acquire additional voting shares for a total of 35 percent, of Southeast Financial Bankstock Corp., and thereby indirectly acquire shares of McGehee Bank, both of McGehee, Arkansas.

Board of Governors of the Federal Reserve System, November 28, 2017.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2017-25908 Filed 11-30-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2017-0114, NIOSH-305]

Draft—National Occupational Research Agenda for Transportation, Warehousing and Utilities

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention announces the availability of a draft NORA Agenda entitled *National Occupational Research Agenda for Transportation, Warehousing and Utilities* for public comment. To view the notice and related materials, visit <https://www.regulations.gov> and enter CDC-2017-0114 in the search field and click "Search."

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Supplementary Information

Background

DATES: Electronic or written comments must be received by January 30, 2018.

ADDRESSES: You may submit comments, identified by CDC-2017-0114 and docket number NIOSH-305, by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH

Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Instructions: All submissions received in response to this notice must include the agency name and docket number [CDC-2017-0114; NIOSH-305]. All relevant comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226-1998.

FOR FURTHER INFORMATION CONTACT:

Emily Novicki (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E-20, 1600 Clifton Road NE., Atlanta, GA 30329, phone (404) 498-2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: The National Occupational Research Agenda (NORA) is a partnership program created to stimulate innovative research and improved workplace practices. The national agenda is developed and implemented through the NORA sector and cross-sector councils. Each council develops and maintains an agenda for its sector or cross-sector.

Background: The National Occupational Research Agenda for Transportation, Warehousing and Utilities (TWU) is intended to identify the research, information, and actions most urgently needed to prevent occupational illnesses and injuries in the TWU sector. The National Occupational Research Agenda for TWU provides a vehicle for stakeholders to describe the most relevant issues, gaps, and safety and health needs for the sector. Each NORA research agenda is meant to guide or promote high priority research efforts on a national level, conducted by various entities, including: Government, higher education, and the private sector.

The first National Occupational Research Agenda for TWU was published in 2009 for the second decade of NORA (2006-2016). This draft is an updated agenda for the third decade of NORA (2016-2026). The revised agenda was developed considering new information about injuries and illnesses, the state of the science, and the probability that new information and approaches will make a difference. As the steward of the NORA process, NIOSH invites comments on the draft *National Occupational Research*

Agenda for TWU. Comments expressing support or with specific recommendations to improve the Agenda are requested. A copy of the draft Agenda is available at <https://www.regulations.gov> (see Docket Number CDC-2017-0114).

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2017-25876 Filed 11-30-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-P-4027]

Determination That METICORTEN (Prednisone) Tablets, 1 Milligram and 5 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that METICORTEN (prednisone) tablets, 1 milligram (mg) and 5 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Meadow Platt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993-0002, 301-796-1830, Meadow.Platt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants

do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

METICORTEN (prednisone) tablets, 1 mg and 5 mg, are the subject of NDA 09-766, held by Schering Corporation (Schering), and initially approved on February 21, 1955. METICORTEN is indicated for the following:

1. *Allergic states:* Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis, serum sickness;

2. *Dermatologic diseases:* Bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome);

3. *Endocrine disorders:* Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance), congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis;

4. *Gastrointestinal diseases:* To tide the patient over a critical period of the disease in regional enteritis and ulcerative colitis;

5. *Hematologic disorders:* Acquired (autoimmune) hemolytic anemia,

Diamond-Blackfan anemia, idiopathic thrombocytopenic purpura in adults, pure red cell aplasia, selected cases of secondary thrombocytopenia;

6. *Miscellaneous:* Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used with appropriate antituberculous chemotherapy;

7. *Neoplastic diseases:* For the palliative management of leukemias and lymphomas;

8. *Nervous system:* Acute exacerbations of multiple sclerosis; cerebral edema associated with primary or metastatic brain tumor, craniotomy, or head injury;

9. *Ophthalmic diseases:* Sympathetic ophthalmia, temporal arteritis, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids;

10. *Renal diseases:* To induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus;

11. *Respiratory diseases:* Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis; and

12. *Rheumatic disorders:* As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis; acute rheumatic carditis; ankylosing spondylitis; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, polymyositis, and systemic lupus erythematosus.

In a letter dated November 1, 2001, Schering requested withdrawal of NDA 09-766 for METICORTEN (prednisone). In the **Federal Register** of October 10, 2002 (67 FR 63107), FDA announced that it was withdrawing approval of NDA 09-766, effective November 12, 2002.

Strides Pharma, Inc., submitted a citizen petition dated July 1, 2017 (Docket No. FDA-2017-P-4027), under 21 CFR 10.30, requesting that the Agency determine whether METICORTEN (prednisone) tablets, 1 mg and 5 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that METICORTEN (prednisone) tablets, 1 mg and 5 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner