

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Practitioner Data Banks, Bureau of Health Professions, Health Resources and Services Administration, Room 8-103, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

NOTIFICATION PROCEDURE:

Information is available upon request, to the persons or entities, or to the authorized agents in such form or manner as the Secretary prescribes. The subject of a report is notified via U.S. mail when a record concerning the individual is submitted to the Data Bank via Subject Notification Document (SND).

REQUESTS BY MAIL:

Practitioners may submit a "Request for Information Disclosure" to the address under system location for any report on themselves. The request must contain the following: Name, address, date of birth, gender, Social Security Number (optional), professional schools and years of graduation, and the professional license(s). For license, include: The license number, the field of licensure, the name of the State or Territory in which the license is held, and DEA registration number(s). The practitioner must submit a signed and notarized self-query request.

PENALTIES FOR VIOLATION:

Submitting a request under false pretenses is a criminal offense and subject to a civil monetary penalty of up to \$11,000 for each violation.

REQUESTS IN PERSON:

Due to security considerations, the Data Bank cannot accept requests in person.

REQUEST BY TELEPHONE:

Practitioners may provide all of the identifying information stated above to the Data Bank Customer Service Center operator. Before the data request is fulfilled, the operator will return a paper copy of this information for verification, signature and notarization.

RECORD ACCESS PROCEDURES:

Request for access of records in the Data Bank may be completed online at: <http://www.npdb-hipdb.hrsa.gov>. The requests are submitted over the web using the Integrated Query and Reporting Service (IQRS), Query and Reporting Extensible Markup Language Service (QRXS), Interface Control Document (ICD) Transfer Program (ITP) or the Proactive Disclosure Service (PDS). Self-query, as described previously, may be initiated via the electronic system and is completed

using the conventional mail system. Requesters, including self-queries, will receive an accounting of disclosure that has been made of their records, if any.

CONTESTING RECORD PROCEDURES:

The Data Bank routinely mails a copy of any report filed in it to the subject individual. A subject individual may contest the accuracy of information in the Data Bank concerning himself or herself and file a dispute. To dispute the accuracy of the information, the individual must contact the Data Bank and the reporting entity to: (1) Request for the reporting entity to file correction to the report; and (2) request the information be entered into a "disputed" status and submit a statement regarding the basis for the inaccuracy of the information in the report. If the reporting entity declines to change the disputed report or takes no actions, the subject may request that the Secretary of HHS review the disputed report. In order to seek a Secretarial Review, the subject must: (1) Provide written documentation containing clear and brief factual information regarding the information of the report; (2) submit supporting documentation or justification substantiating that the reporting entity's information is inaccurate; and (3) submit proof that the subject individual has attempted to resolve the disagreement with reporting entity but was unsuccessful. The Department can only determine whether the report was legally required to be filed and whether the report accurately depicts the action taken and the reporter's basis for action. Additional detail on the process of dispute resolution and Secretarial Review process can be found at 45 CFR § 60.14 of the Data Bank regulations.

RECORD SOURCE CATEGORIES:

The records contained in the system are submitted by the following entities: (1) Insurance companies and others who have made payment as a result of a malpractice action or claim, (2) State Boards of Medical and Dental Examiners; (3) State Licensing Boards; (4) hospitals and other health care entities; (5) DEA; and (6) Federal entities which employ health practitioners or who have authority to sanction such practitioners covered by a Federal program. Section 1921 of the Social Security Act expands reporting of actions submitted by State health care practitioner licensing and certification authorities (including medical and dental boards), State entity licensing and certification authorities, peer review organizations and private accreditation organizations.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2010-24568 Filed 9-30-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-N-0506]

Office of the Commissioner; Request for Comments on the Food and Drug Administration Fiscal Year 2011-2015 Strategic Priorities Document; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking public comment on its draft Strategic Priorities FY 2011-2015. FDA has identified these strategic priorities and goals that will guide its efforts to achieve its public health mission. FDA is seeking public comment to help further refine these priorities and goals.

DATES: Submit either electronic or written comments by November 1, 2010.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Darian Tarver, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4219, Silver Spring, MD 20993-0002, 301-796-4850.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is posting its draft Strategic Priorities FY 2011-2015 to ensure that key stakeholders are given an opportunity to comment on this document.

The purpose of this document is to outline FDA's strategic intentions and plans for the next 5 years (fiscal year (FY) 2011 through 2015). This document identifies four key cross-cutting strategic priorities and four strategic program goals that will guide efforts to achieve FDA's public health mission and to fulfill its role in supporting the larger mission and strategic goals of the Department of

Health and Human Services. The four cross-cutting strategic priorities are: (1) Advance Regulatory Science and Innovation, (2) Strengthen the Safety and Integrity of the Global Supply Chain, (3) Strengthen Compliance and Enforcement Activities to Support Public Health, and (4) Expand Efforts to Meet the Needs of Special Populations. The four strategic program goals are: (1) Advance Food Safety and Nutrition, (2) Promote Public Health by Advancing the Safety and Effectiveness of Medical Products, (3) Establish an Effective Tobacco Regulation, Prevention, and Control Program, and (4) Manage for Organizational Excellence and Accountability.

The strategic planning process is an opportunity for FDA to further refine and strengthen the strategic management structure currently in place. For comparison purposes, the current FDA Strategic Action Plan 2007 can be viewed at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM061415.pdf>.

FDA has made significant progress in its strategic planning efforts. As we build on this progress we look forward to receiving your comments by (see **DATES**). The text of the draft strategic priorities document is available in a "pdf" (portable document format) downloadable format through FDA's Web site: <http://www.fda.gov/AboutFDA/>.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-24603 Filed 9-30-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0257]

Single-Ingredient Oral Colchicine Products; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or agency) is announcing its intention to take enforcement action against unapproved single-ingredient oral colchicine products and persons¹ who manufacture or cause the manufacture of such products or their shipment in interstate commerce. Unapproved single-ingredient oral colchicine products have been associated with serious adverse events, including fatalities. Single-ingredient oral colchicine products are new drugs that require approved applications because they are not generally recognized as safe and effective. Currently one firm has obtained approved applications to market single-ingredient oral colchicine for the treatment of acute gout flares, prophylaxis of gout flares, and prophylaxis of attacks of Familial Mediterranean Fever (FMF). All other manufacturers who wish to market single-ingredient oral colchicine products for these or other indications must obtain FDA approval of a new drug application (NDA) or an abbreviated new drug application (ANDA).

DATES: This notice is effective October 1, 2010. For information about enforcement dates, see **SUPPLEMENTARY INFORMATION**, section III.C.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA-2010-N-0257 and directed to the appropriate office listed as follows:

Regarding applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)): Division of Anesthesia,

Analgesia and Rheumatology Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993-0002.

All other communications: See the **FOR FURTHER INFORMATION CONTACT** section of this document.

¹A "person" includes individuals, partnerships, corporations, or associations (section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(e)).

FOR FURTHER INFORMATION CONTACT:

Karen Rothschild, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5237, Silver Spring, MD 20993-0002, 301-796-3689, e-mail: Karen.Rothschild@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Colchicine is an alkaloid of the *Colchicum autumnale* plant, also known as autumn crocus or meadow saffron. Colchicum was initially described in the 1st century A.D. by Dioscorides in the *Materia Medica*. Medical use of colchicum for gout pain dates back to the 6th century. It was used for several centuries, but the use of colchicum in the treatment of gout substantially declined by the 15th century because of its toxicity. Colchicum was reintroduced as a treatment for acute gout beginning in 1763. Colchicine was first isolated from colchicum in 1820 and made available in oral dosage form during the 19th century. Colchicine in oral dosage form is currently marketed in the United States as approved and unapproved products, both as a single ingredient and in combination with probenecid. Colchicine for injection has been available in the United States since the 1950s and has been administered intravenously for the treatment of acute gout flares. In the **Federal Register** of February 8, 2008 (73 FR 7565), FDA announced its intention to take enforcement action against unapproved drug products containing colchicine for injection. Single-ingredient oral colchicine products, the subject of this notice, have also been marketed in the United States without approved applications to treat acute gout flares, and are more commonly marketed in conjunction with uric acid lowering agents for the daily prophylaxis of flares of gout. Daily oral colchicine has also been the standard of care since the 1970s for the prophylaxis of attacks of FMF.

One firm, Mutual Pharmaceutical Co., Inc. (Mutual), of Philadelphia, PA, has received approval for three NDAs for single-ingredient oral colchicine. These approvals are: NDA 22-352 for the treatment of FMF,² approved on July 29,

²Because the incidence of FMF in the United States is rare, Mutual sought and was granted orphan drug status for its product covered by NDA 22-352 under section 526 of the act (21 U.S.C. 360bb). The term "orphan drug" refers to a product that treats a rare disease affecting fewer than 200,000 Americans. Enacted in 1983, the intent of the Orphan Drug Act is to stimulate the research, development, and approval of products that treat