Guidance	Date of Issuance
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP	April 1995
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP	April 1995
Fludeoxyglucose F18 Injection	January 1997
Flurbiprofen Tablets USP	Revised January 1994
Fluvoxamine Maleate Tablets	September 1997
Gentamicin Sulfate Ophthalmic Solution USP and Gentamicin Sulfate Ophthalmic Ointment USP	Revised April 1992
Heparin Sodium Injection USP	Revised March 1991
Hydrocodone Bitartrate and Acetaminophen Tablets USP	Revised April 1994
Indomethacin Capsules USP	Revised September 1995
Itraconazole Capsules	September 1998
Leucovorin Calcium for Injection	July 1996
Leucovorin Calcium Tablets USP	July 1996
Medroxyprogesterone Acetate Tablets USP	Revised September 1998
Metaproternol Sulfate Inhalation Solution USP	Revised May 1992
Metaproterenol Sulfate Syrup USP	Revised May 1992
Metaproterenol Sulfate Tablets USP	Revised May 1992
Metoclopramide Tablets USP and Metoclopramide Oral Solution USP	Revised February 1995
Naproxen Sodium Tablets USP	September 1997
Naproxen Tablets USP	September 1997
Paclitaxel Injection	September 1997
Quinidine Sulfate Tablets, USP	October 1995
Ranitidine Tablets USP	Revised November 1993
Risperidone Oral Solution	September 1997
Risperidone Tablets	September 1997
Sulfacetamide Sodium Ophthalmic Solution USP and Sulfacetamide Sodium Ophthalmic Ointment USP	Revised August 1993
Sulfacetamide Sodium and Prednisolone Acetate	Revised January 1995
Sulfamethoxazole and Trimethoprim Tablets USP and Sulfamethoxazole and Trimethoprim Oral Suspension USP	Revised August 1993
Theophylline	Revised February 1995
Theophylline Intravenous Dosage Forms	September 1995
Tobramycin Sulfate Injection USP	Revised May 1993
Venlafaxine Hydrochloride Tablets	October 1997
Verapamil Hydrochloride Tablets	October 1991
Zolpidem Tartrate Tablets	September 1997

In May 2000, the agency issued the guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' This guidance provides information on how to access current package insert labeling on OGD's Labeling Review Branch Web site at http://www.fda.gov/cder/ogd/rld/labeling_review_branch.htm.

Interested persons may submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any 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. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain CDER guidance documents at http://www.fda.gov/cder/guidance/index.htm.

Dated: June 24, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16796 Filed 7–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1454]

Guidance for Industry on Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation.'' This document provides guidance for industry on the chemistry, manufacturing, and controls documentation that should be submitted in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for nasal spray and inhalation solution, suspension, and spray drug products intended for local and/or systemic effect. The guidance also provides recommendations on labeling.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Guirag Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation.'' This guidance provides recommendations on the information that should be submitted in NDAs and ANDAs for these products, including information on drug product components, manufacturing process, and the associated controls. However, it does not address the manufacture of drug substances. The guidance gives recommendations on information that should be provided to ensure continuing quality and performance characteristics for these drug products. This guidance also provides information on labeling.

In the **Federal Register** of June 2, 1999 (64 FR 29657), FDA announced the availability of a draft version of this guidance. The June 1999 guidance gave interested persons an opportunity to submit comments through August 31, 1999. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, the guidance is clearer and more concise than the draft version. FDA is participating in research relating to these types of drug products through the Product Quality Research Institute (Internet address at http://www.pqri.org) and will evaluate whether to update the guidance as information from this research becomes available.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on chemistry, manufacturing, and controls documentation for nasal spray and inhalation solution, suspension, and spray drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any 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. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: June 24, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16797 Filed 7–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Radio Frequency Cauterization Biopsy

Bradford J. Wood and Christan Pavlovich (CC)

DHHS Reference Nos. E–207–01/0 filed Oct 17, 2001 and E–207–01/1 filed Apr 08, 2002

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: *berkleyd@od.nih.gov.*

The invention is a method and apparatus for using radio frequency (RF) energy to cauterize the needle track after percutaneous image-guided needle biopsy using an RF ablation probe. The invention is designed to limit the risks of bleeding and needle track seeding that are inherent risks of any needle biopsy. The device uses a coaxial biopsy arrangement with the outer needle coated with a non-conducting polymer that insulates the needle shaft and the tissue immediately in contact with the shaft. As the needle is pulled back from the organ or tumor target, RF energy is applied to an exposed end portion of the probe, causing cauterization and coagulation of the tissue immediately adjacent to the needle track. A variation on the device could be used to limit bleeding after catheter placement into organs, such as for nephrostomy, biliary drainage, or transhepatic islet cell transplantation.

Method and Apparatus for Countercurrent Chromatography

Yoichiro Ito (NHLBI)

DHHS Reference No. E–148–01/0 filed Apr 05, 2002

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: *berkleyd@od.nih.gov.*

This invention is an improved column design for High Speed Counter Current Chromatography (HSCCC) that increases partition efficiency by using novel tubing geometries. A standard HSCCC centrifuge uses a multilayer coil as a separation column to produce a high efficiency separation with good retention of the stationary phase in many solvent systems. However, the standard HSCCC, when used for highly viscous, low interfacial solvent systems, is unsuccessful at retaining a suitable amount of the stationary phase. This invention greatly improves efficiency by modifying the column from a coil to spiral geometry. Thereby, this invention creates a centrifugal force gradient, which allows for distribution of the heaver phase in the peripheral and the lighter phase in the proximal part of the column. The effect of the gradient becomes more pronounced as the pitch of the spiral is increased.

Method for Segmenting Medical Images and Detecting Surface Anomalies in Anatomical Structures

Ronald M. Summers et al. (CC)

U.S. Patent 6,246,784 issued Jun 12, 2001; U.S. Patent 6,345,112 issued Feb 05 2002; Serial No. 10/072,667 filed Feb 05, 2002

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: *berkleyd@od.nih.gov.*