

PHARMACOPEIAL FORUM

32 NUMBER 2

BIMONTHLY: March–April 2006

Featured in This Issue

USP has identified the following content areas in the March-April 2006 issue of *Pharmacoepial Forum* as noteworthy for the pharmaceutical industry worldwide.

- Policies and Announcements
 - PF Online launches new “My PF” product enhancement
- Second Interim Revision Announcement
 - Harmonization of General Information *Chapter <1216> Tablet Friability*
- In-Process Revision
 - General Information *Chapter <1047> Biotechnology Derived Articles--Tests* to be split into 6 separate General Chapters
 - 14 USP monographs
 - 3 NF Monographs

A detailed listing of the Table of Contents of the March-April issue of *Pharmacoepial Forum* follows.



U.S. PHARMACOPEIA
The Standard of QualitySM

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STAFF DIRECTORY

This updated directory reflects assignment changes based on 2005–2010 Expert Committees. The general USP telephone number, (301) 881-0666, may still be used for general inquiries or when a particular Expert Committee is not identified. The fax number is (301) 816-8373.

STAFF	E-MAIL	PHONE	ASSIGNMENT
Clydewyn M. Anthony, Ph.D., Scientist	cma@usp.org	(301) 816-8139	Monograph Development— Cough, Cold, and Analgesics (MD-CCA)
Shawn C. Becker, B.S.N., Director, Patient Safety	scb@usp.org	(301) 816-8216	Safe Medication Use
Daniel K. Bempong, Ph.D., Scientist	dkb@usp.org	(301) 816-8143	Pulmonary and Steroids (MD-PS)
Lokesh Bhattacharyya, Ph.D., Director, Non-Complex Actives and Excipients	lb@usp.org	(301) 816-8201	
Barbara A. Bowman, Manager, Administrative Services	bab@usp.org	(301) 816-8278	USP Correspondence
William E. Brown, Senior Scientist	web@usp.org	(301) 816-8380	Biopharmaceutics (BPC); Pharmaceutical Dosage Forms (PDF)
Evelyn Bryant, Manager, Editorial Services	eb@usp.org	(301) 816-8302	
Damian A. Cairatti, Senior Scientific Associate	dac@usp.org	(301) 816-8307	USP Spanish Edition; Dietary Supplements—Bioavailability (DS-BA); Dietary Supple- ments—General Chapters (DS-GC)
Larry N. Callahan, Ph.D., Scientist	lnc@usp.org	(301) 816-8385	B&B Proteins and Polysaccha- rides (BB PP)
Antonio Hernandez-Cardoso, Scientist, Latin American Specialist	ahc@usp.org	(301) 816-8308	USP Spanish Edition; General Chapters (GC)
Todd L. Cecil, Ph.D., Vice President, Standards Development	tlc@usp.org	(301) 816-8234	
Roger Dabbah, Ph.D., Scientific Fellow	rd@usp.org	(301) 816-8336	
Behnam Davani, Ph.D., Senior Scientist	bd@usp.org	(301) 816-8394	Monograph Development— Antivirals and Antimicrobials (MD-AA)
Ian F. DeVeau, Ph.D., Associate Director, Complex Actives	ifd@usp.org	(301) 816-8178	Biologics and Biotechnology— Blood and Blood Products (BB BBP); Veterinary Drugs (VET); Veterinary Medicine Information (VMI)
Shawn F. Dressman, Ph.D., Director, Reference Standards Evaluation	sfd@usp.org	(301) 816-8261	Reference Standards (RS)
Lawrence Evans, Ph.D., Scientist	le@usp.org	(301) 816-8389	Dietary Supplements—General Chapters (DS-GC); Dietary Supplements—Non- Botanicals (DSN)
L. Valentin Feyns, Ph.D., Scientific Fellow	lvf@usp.org	(301) 816-8121	Reference Standards (RS)

STAFF DIRECTORY (continued)

STAFF	E-MAIL	PHONE	ASSIGNMENT
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Brian D. Gilbert, Ph.D. , Scientist	bg@usp.org	(301) 816-8223	Monograph Development— Antibiotics (MD-ANT)
Elena Gonikberg, Ph.D. , Senior Scientist	eg@usp.org	(301) 816-8251	Gastrointestinal, Renal, and Endocrine (MD-GRE)
Desmond G. Hunt, Ph.D. , Senior Scientific Associate	dgh@usp.org	(301) 816-8341	Packaging and Storage (P&S)
James W. Kelly, Ph.D. , Scientist	jwk@usp.org	(301) 816-8167	Parenteral Products—Industrial (PPI)
Sujatha Ramakrishna, Ph.D. , Scientist	syk@usp.org	(301) 816-8349	Monograph Development— Cardiovascular (MD-CV)
Christina H. Lee, Ph.D. , Senior Scientific Associate	chl@usp.org	(301) 816-8335	Compounding Pharmacy (CRX); Sterile Compounding (SCC)
Angela G. Long , Vice President, Volunteer and Organizational Affairs and Executive Secretariat	agl@usp.org	(301) 816-8382	
Anju K. Malhotra , Manager, Scientific Administration	akm@usp.org	(301) 816-8346	
Ronald G. Manning, Ph.D. , Vice President, Monograph and Reference Standard Development	rgm@usp.org	(301) 816-8562	
Feiwen Mao , Senior Scientific Associate	fm@usp.org	(301) 816-8320	Monograph Development— Ophthalmology, Oncology, and Dermatology (MD-OOD)
Margareth R. Marques, Ph.D. , Senior Scientist and Latin American Liaison	mrm@usp.org	(301) 816-8106	Biopharmaceutics (BPC); Pharmaceutical Dosage Forms (PDF); Chromatographic Reagents
Marcia D. Mayfield , Manager, Monograph Development	mxm@usp.org	(301) 816-8358	
Kevin Moore, Ph.D. , Scientist	ktm@usp.org	(301) 816-8369	Harmonization; Monograph Improvement
Tina S. Morris, Ph.D. , Director, Complex Actives	tsm@usp.org	(301) 816-8397	B&B Vaccines and Virology (BB-VV)
Alan W. Nichols, Ph.D. , Director, Reference Standards Production	awn@usp.org	(301) 816-8321	USP Reference Standards
Claudia C. Okeke, Ph.D. , Associate Director, General Policies and Requirements Division	cco@usp.org	(301) 816-8243	Compounding Pharmacy Sterile Compound- ing (SCC)
Horacio Pappa, Ph.D. , Scientist and Latin American Liaison	hp@usp.org	(301) 816-8319	General Chapters (GC); Statistics (STAT)
W. Larry Paul, Ph.D. , Scientific Fellow	wlp@usp.org	(301) 816-8331	Nomenclature (NOM)
David A. Porter, Ph.D. , Director, General Policies and Requirements	dap@usp.org	(301) 816-8225	

STAFF DIRECTORY (continued)

STAFF	E-MAIL	PHONE	ASSIGNMENT
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Gary E. Ritchie, M.S., Scientific Fellow for PAT	ger@usp.org	(301) 816-8353	General Chapters (GC); Pharmaceutical Waters (PW); Statistics (STAT)
Karen A. Russo, Ph.D., Associate Director, Monograph Acquisition and Infrastructure	kar@usp.org	(301) 816-8379	Monograph Acquisition and Infrastructure
Stefan P. Schuber, Ph.D., Director, Scientific Reports	sps@usp.org	(301) 816-8551	
Maged H. M. Sharaf, Ph.D., Senior Scientist	mhs@usp.org	(301) 816-8318	Dietary Supplements— Botanicals (DSB); Dietary Supplements— General Chapters (DS-GC)
Catherine M. Sheehan, Scientist	cxs@usp.org	(301) 816-8262	Excipient Monographs 1 (EM1); Excipient General Chapters (EGC); Harmonization
Eric B. Sheinin, Ph.D., USP Fellow	es@usp.org	(301) 816-8103	
Anita Y. Szajek, Ph.D., Senior Scientist	aey@usp.org	(301) 816-8325	B&B Cell, Gene, and Tissue Therapies (BB CGT)
Radhakrishna S. Tirumalai, Ph.D., Scientist	rst@usp.org	(301) 816-8339	General Toxicity and Medical Device Biocompatibility (GTMDB); Microbiology and Sterility Assurance (MSA)
Beryl Voigt, Director, Executive Secretariat	bev@usp.org	(301) 816-8155	
Hong Wang, Ph.D., Senior Scientific Associate	hw@usp.org	(301) 816-8351	Excipient Monographs 2 (EM2); Excipient General Chapters (EGC)
Andrzej Wilk, Ph.D., Scientist	aw@usp.org	(301) 816-8305	Radiopharmaceuticals and Medical Imaging Agents (RMI); Radiopharmaceutical Information (RI)
Kahkashan Zaidi, Ph.D., Scientist	kxz@usp.org	(301) 816-8269	Aerosols (AER); General Chapters (GC)

PF ONLINE LAUNCHES NEW “MY PF” PRODUCT ENHANCEMENT. Beginning in March 2006, *PF Online* subscriptions will include “My PF”—a value-added enhancement that allows users to save searches and bookmarks. This new option is FREE to *PF Online* subscribers and is provided in addition to standard Web-based features, including current issue search, advanced search, browse, print, and copy-paste. With “My PF,” *PF Online* users can perform the following functions:

- Set up searches for specific *USP–NF* monographs or general chapters to find out if any recent changes have occurred in areas that impact their work.
- Run historical searches to track the progression of changes and chart comparisons. *PF Online* provides access to back issues, beginning with 2002.
- Bookmark monographs for easy access in the future.
- Bookmark frequently accessed information such as comment deadlines and liaison contact information.
- Find out if a new Reference Standard has been released by creating a search and run each time a new *PF Online* edition becomes available.

For subscription information and additional details about *PF Online*, please visit <http://www.usp.org/products/PF/> or contact USP Customer Service at 1-800-227-8772 or +1-301-881-0666.

NOTICE OF CORRECTION TO HELIUM, NITROUS OXIDE, NITROGEN, AND NITROGEN 97 PERCENT MONOGRAPHS. Because the revisions to these monographs, which were published in the *First Supplement* to *USP 28–NF 23* have been postponed indefinitely, *USP 29–NF 24* by default should have shown the *Identification* and *Assay* tests as they originally appeared in the *USP 28–NF 23* on pages 939, 1388, 3041, and 3041, respectively. Instead, these sections of the monographs were printed in error without the original text. See the USP website www.usp.org/USPNF/notices/ for the original text.

Should you have any questions, please contact Kahkashan Zaidi, Ph.D., Senior Scientist, General Policies and Requirements Division (301-816-8269 or kxz@usp.org).

GENERAL CHAPTERS (1) AND (905) POSTPONEMENTS—CLARIFICATION. Two postponements that appeared in the *Fifth IRA* and *Sixth IRA*, respectively for (1) *Injections* and (905) *Uniformity of Dosage Units* do not appear as postponed in the *USP 29–NF 24*. This is due to USP’s publication schedule, which slates the *Fifth IRA* and *Sixth IRA* for the *First Supplement* to *USP 29–NF 24*, rather than to the book. The *First Supplement* is scheduled to be published on February 15, 2006, and become official on April 1, 2006. The complete publication schedule appears in this section of *PF*.

For General Chapter (1) *Injections*, USP has postponed the text for *Printing on Ferrules and Cap Overseals* that was to become official on October 1, 2005, as stated in *USP 28–NF 23*. The reason for the postponement is that the Parenteral Products—Industrial, Nomenclature, and Safe Medication Use Expert Committees have approved a revision of this section that also appears in *Pharmacopeial Forum* 31(5), with an implementation date of February 1, 2009.

For General Chapter (905) *Uniformity of Dosage Units*, USP has postponed the official date from April 1, 2006 to January 1, 2007, to provide additional time for the Pharmacopeial Discussion Group to evaluate comments received concerning this revision.

Further information about these postponements is available on USP’s website (www.usp.org). If you have any questions, please contact Beryl Voigt, Director, Executive Secretariat (301-816-8155 or bev@usp.org).

USP ISSUES NOTICE OF RETRACTION FOR RESIDUAL SOLVENTS. Please note the following retraction notice that has been included on page 14 of the *USP 29–NF 24*.

“Residual Solvents (467): meet the requirements.” is hereby withdrawn from all monographs in the USP and the NF. This retraction is made to allow the USP Council of Experts further time to evaluate the most appropriate manner to implement the Residual Solvents test. The General Notices statement concerning the application of Residual Solvents to all monographs is unaffected by this retraction.

This notice also serves as an additional request for comments on this issue from all users of the USP. Please forward your comments to:

*Todd Cecil, Ph.D.
Vice President
Department of Standards Development
USP
12601 Twinbrook Parkway
Rockville, MD 20852*

Comments must be received by June 1, 2006 to ensure consideration.

EXPERT COMMITTEE SUMMARIES AVAILABLE ON THE USP WEBSITE. Summaries of the first meetings of the cycle for the 2005–2010 Standards Expert Committees are now posted and available at <http://www.usp.org/USPNF/meetingSummaries/>.

USP SEEKS SUBMISSION OF PROPOSALS FOR STABILITY-INDICATING ASSAY PROCEDURES FOR STEROIDS. The assay procedures for steroids in many *USP–NF* monographs are not stability indicating. In an effort to update the monographs, the Monograph Development—Pulmonary and Steroids Expert Committee is seeking submission of proposals for stability-indicating assay procedures for steroids, preferably HPLC- or GC-based, for inclusion in the following *USP–NF* monographs to replace the current procedures that are not stability indicating. The submissions should include data and other information recommended in the *USP Guideline for Submitting Requests for Revision to the USP–NF* at <http://www.usp.org/pdf/EN/USPNF/revisionGuide.pdf>. Each submission should include analytical validation data, data demonstrating that the procedure is stability indicating, and results of analysis from three commercial batches. Please submit proposals for steroid assay procedures for the following *USP–NF* monographs to Daniel Bempong, Ph.D., or contact him for the details at 301-816-8143 or dkb@usp.org.

Drug Substance:

Clocortolone Pivalate
Danazol
Desoxycorticosterone Acetate
Estriol
Fludrocortisone Acetate
Flumethasone Pivalate
Hydrocortisone Sodium Phosphate
Hydrocortisone Sodium Succinate
Hydroxyprogesterone Caproate
Levonorgestrel
Meprednisone
Mestranol
Methylprednisolone Sodium Succinate
Nandrolone Phenpropionate
Norethindrone
Norethindrone Acetate
Norethynodrel
Norgestrel
Oxandrolone
Oxymetholone
Paramethasone Acetate
Prednisolone Hemisuccinate
Prednisolone Sodium Phosphate
Testosterone
Testosterone Enanthate
Testosterone Propionate

Dosage Form:

Betamethasone Oral Solution
Clocortolone Pivalate Cream
Desoxycorticosterone Acetate Injection
Desoxycorticosterone Acetate Pellets
Dexamethasone Gel
Dexamethasone Sodium Inhalation Aerosol
Dexamethasone Tablets

Dexamethasone Topical Aerosol
Estradiol Injectable Suspension
Estradiol Tablets
Estrone Injection
Flumethasone Pivalate Cream
Hydrocortisone Acetate Injectable Suspension
Hydrocortisone Acetate Ophthalmic Ointment
Hydrocortisone Acetate Ophthalmic Suspension
Hydrocortisone Injectable Suspension
Hydrocortisone Sodium Phosphate Injection
Hydroxyprogesterone Caproate Injection
Methylprednisolone Acetate Cream
Methyltestosterone Capsules
Methyltestosterone Tablets
Nandrolone Phenpropionate Injection
Norethindrone Acetate Tablets
Norethindrone Acetate and Ethinyl Estradiol Tablets (assay for both steroids)
Norethindrone Tablets
Norgestrel Tablets
Oxymetholone Tablets
Paramethasone Acetate Tablets
Penicillin G Procaine, Dihydrostreptomycin Sulfate, and Prednisolone Injectable Suspension (assay for Prednisolone)
Neomycin Sulfate, Sulfacetamide Sodium, and Prednisolone Acetate Ophthalmic Ointment (assay for Prednisolone Acetate)
Prednisolone Sodium Phosphate Injection
Prednisolone Sodium Phosphate Ophthalmic Solution
Neomycin Sulfate and Prednisolone Sodium Phosphate Ophthalmic Ointment (assay for Prednisolone Sodium Phosphate)
Prednisolone Sodium Succinate for Injection
Prednisolone Cream
Progesterone Intrauterine Contraceptive System
Testosterone Enanthate Injection
Testosterone Injectable Suspension
Testosterone Propionate Injection

PHARMACOPEIAL EDUCATION COURSES. USP's Pharmacopeial Education courses offer specialized instruction for chemists, other scientists, and professionals in the pharmaceutical and allied industries. USP scientists who play a key role in establishing official USP standards teach these courses and provide expert insights on the practical applications of official test procedures and best practices in using the *USP–NF* and other USP resources. The courses also give participants an opportunity to learn how to get involved in USP's standards-setting processes and the benefits of participating in standards development. Courses offered in 2006 are listed below. For more information and to register, visit www.usp.org. To discuss how USP can bring courses to a location of your choice or design a custom course package for you, call 301-816-8237, or e-mail PharmacopeialEducation@usp.org.

2006 Calendar of Pharmacopeial Education Courses

Date	Name of Course	Location	Price
18-Jan-06	Effectively Using the <i>USP–NF</i>	California State University—Fullerton, CA	\$595
24-25 Jan-06	Fundamentals of Dissolution—Lecture & Lab	North Brunswick, NJ	\$1,500
14-Feb-06	Effectively Using the <i>USP–NF</i>	Basel, Switzerland	\$595
15-Feb-06	Analytical Method Validation	Basel, Switzerland	\$595
23-Feb-06	Effectively Using the <i>USP–NF</i>	North Carolina State University—Raleigh, NC	\$595
29-Mar-06	Basic Statistics and their Practical Applications to the <i>USP–NF</i>	New Jersey, hosted by NJPQCA	\$595
19-Apr-06	Effectively Using the <i>USP–NF</i> —Session I	USP Headquarters, Rockville, MD	\$895
20-Apr-06	Effectively Using the <i>USP–NF</i> —Session II	USP Headquarters, Rockville, MD	\$895 (\$1,695 both days)

VISIT THE USP WEB SITE AT (<http://www.usp.org>). Various resources related to Pharmacopeial standards are presented, including highlights from *PF*.

INTERNATIONAL CORRESPONDENCE. Individuals who wish to correspond with the European and Japanese Pharmacopoeias concerning monographs in the Official Inquiry and Consensus stages of international harmonization should address their comments to the coordinating pharmacopeia, with a copy to USP, for a given article. The addresses for the European and Japanese Pharmacopoeias are as follows:

Technical Secretariat of the European
Pharmacopoeia Commission
B.P. 907
F 67029 Strasbourg Cedex 1
France

NAKASHIMA Nobumasa
Evaluation and Licensing Division
Pharmaceutical and Medical Safety Bureau
Ministry of Health, Labour and Welfare, Japan
Tel. +81-3-3595-2431, Fax +81-3-3597-9535
E-mail: nakashima-nobumasa@mhlw.go.jp

HOW TO SUBMIT COMMENTS. The USP welcomes and encourages interested parties to submit comments and data regarding potential, proposed, or adopted (official) standards. Submissions concerning a particular item that has appeared in an issue of *PF* should be submitted to the appropriate USP scientific staff liaison identified at the end

of the *Briefing* accompanying each item. To submit comments and data to a liaison, use the e-mail address and telephone numbers listed in the *Staff Directory* included in every *PF*.

Please note that *USP–NF* is being published in an annual edition with one main book and two *Supplements* a year. In addition, the schedule provided below will repeat every year so that users will know what to expect and become familiar with the deadlines.

In the future, USP anticipates including the comment submission deadline in each briefing of every revision proposal when it is published for public review and comment.

For general inquiries or in cases where a particular liaison is not identified, use the general USP telephone number 301-881-0666 or FAX number 301-816-8373.

NEW PHARMACOPEIAL FORUM PUBLIC REVIEW AND COMMENT PERIOD DEADLINES. The full year's listing of comment period deadlines and the targeted official publications appear below. In accordance with the Rules and Procedures of the 2005–2010 Council of Experts*, USP is implementing the 90-day comment period by providing a deadline for each issue of *PF* unless otherwise stated in the individual briefing. Note that *PF* 31(6) and *PF* 32(1) have a combined comment deadline (April 17, 2006) due to the omission of the comment deadline dates in *PF* 31(6). Individual comment deadlines begin with *PF* 32(2) [Mar.–Apr. 2006].

* *Section 9.04(b) of the Rules and Procedures of the 2005–2010 Council of Experts*

A period of at least ninety (90) days from the date of publication will be allowed for public review and comment. The time allowed for public comments shall be noted in the publication in the PF. For good cause shown, the Chairperson may alter the time specified.

The listing of comment period deadlines and the targeted official publications appear below.

Pharmacopeial Forum	Comment Deadline	Targeted Official Publication	Publication Date	Official Date
PF 31(6)	April 17, 2006	USP 30–NF 25	November 2006	January 2007
PF 32(1)	April 17, 2006			
PF 32(2)	June 15, 2006	USP 30–NF 25 1st Supplement	February 2007	April 2007
PF 32(3)	August 15, 2006			
PF 32(4)	October 16, 2006	USP 30–NF 25 2nd Supplement	June 2007	August 2007
PF 32(5)	December 15, 2006			
PF 32(6)	February 15, 2007	USP 31–NF 26	November 2007	January 2008
PF 33(1)	April 16, 2007			
PF 33(2)	June 15, 2007	USP 31–NF 26 1st Supplement	February 2008	April 2008

All official revisions are published in the annual edition or *Supplements* to *USP–NF* (twice yearly). Between these publications, official revisions are published in *PF* in the *Interim Revision Announcement*; these revisions are also incorporated in the upcoming *Supplement*. The official publication in which an *IRA* is incorporated will depend upon publication deadlines. The 5th *IRA* and the 6th *IRA* will not appear until *Supplement 1*. See table below. The electronic version of *USP–NF* is updated as each *Supplement* becomes available and, therefore, contains all official text up to and including the contents of the latest *Supplement*. The new table below outlines the publications and their release and official dates, and the book or supplement which supersedes them.

Publication Schedules

Publication	Release Date	Official Date	Superseded by
USP 29–NF 24	Nov. 1, 2005	Jan. 1, 2006	1st Supplement
1st Supplement	Feb. 1, 2006	Apr. 1, 2006	2nd Supplement
1st IRA [PF 32(1)]	Jan. 1, 2006	Feb. 1, 2006	2nd Supplement
2nd IRA [PF 32(2)]	Mar. 1, 2006	Apr. 1, 2006	2nd Supplement
3rd IRA [PF 32(3)]	May 1, 2006*	June 1, 2006*	USP 30–NF 25
2nd Supplement	June 1, 2006*	Aug. 1, 2006*	USP 30–NF 25
4th IRA [PF 32(4)]	July 1, 2006*	Aug. 1, 2006*	USP 30–NF 25
5th IRA [PF 32(5)]	Sept. 1, 2006*	Oct. 1, 2006*	1st Supplement USP 30–NF25
6th IRA [PF 32(6)]	Nov. 1, 2006*	Dec. 1, 2006*	1st Supplement USP 30–NF25
USP 30–NF 25	Nov. 1, 2006*	Jan. 1, 2007*	

*Tentative

CALL FOR HIGH PRIORITY MONOGRAPHS FOR DRUG SUBSTANCES AND PRODUCTS AND EXCIPIENTS. USP is seeking monographs for the following drug substances and drug products that are or soon will be off patent and thus are of the highest priority. USP also is seeking monographs for the excipients listed below. Monographs are marked received upon receipt of a monograph proposal. Received monographs are removed from this list upon publica-

tion in *Pharmacopeial Forum*. (This list has been updated as of December 15, 2005). This list is also available on the USP website at <http://www.usp.org/USPNF/submitMonograph/newMon.html>. For further information, contact Karen Russo, Ph.D., kar@usp.org. Monograph sponsors should consult the *USP Guideline for Submitting Requests for Revision to the USP–NF* at <http://www.usp.org/pdf/EN/USPNF/revisionGuide.pdf>.

Noncomplex Actives (Drug Substances)

Acarbose	Alatrofloxacin Mesylate	Alfuzosin
Allopurinol Sodium	Aminopromazine Fumarate	Aminopterin Sodium
Amlodipine Besylate <i>(Received)</i>	Anagrelide Hydrochloride <i>(Received)</i>	Arsenic Trioxide
Azelaic Acid	Balsalazide Disodium	Bentoquatam
Bepidril Hydrochloride	Bivalirudin	Cabergoline
Calcipotriene	Calcium Trisodium Pentetate	Calfactant
Candesartan Cilexetil	Carmustine	Carvedilol
Cefdinir	Cefditoren Pivoxil	Ceftibuten
Cetirizine Hydrochloride <i>(Received)</i>	Cetrotorelix	Cevimeline
Chloroxine	Colfosceril	Cytarabine Liposome
Dalfopristin	Dantrolene Sodium <i>(Received)</i>	Dapirazole Hydrochloride
Desirudin	Dexrazoxane	Difloxacin Hydrochloride
Docosanol	Entacapone	Epoprostenol
Erythromycin Phosphate	Erythromycin Thiocyanate	Esomeprazole Magnesium
Esmolol	Estazolam	Estramustine Phosphate Sodium
Estradiol Benzoate	Ethanolamine Oleate	Etomidate
Etoposide Phosphate	Exemestane	Felbamate
Fluoromethane F 18	Foscarnet Sodium	Fosfomycin Tromethamine
Gadobenate Dimeglumine	Galantamine Hydrobromide	Gadopentetic Acid
Gallium Nitrate	Ganirelix	Glyceril Aminobenzoate
Granisetron	Halobetasol Propionate	Haloperidol Decanoate <i>(Received)</i>
Hydrocodone Polistirex	Ibandronate Sodium	Imipramine Pamoate
Imiquimod	Irinotecan	Isosulfan Blue
Itraconazole	Lamotrigine <i>(Received)</i>	Latanoprost
Lawsone	Levetriacepam	Levobetaxolol
Levofloxacin <i>(Received)</i>	Levomethadyl Acetate	Lomustine
Lopinavir	Metipranolol Hydrochloride	Midazolam Hydrochloride
Miglitol	Mifepristone	Misoprostol <i>(Received)</i>
Mivacurium	Moexipril	Nalbuphine Hydrochloride
Nalmefene Hydrochloride	Nateglinide	Nedocromil
Nicardipine Hydrochloride	Nilutamide	Nisoldipine
Olopatadine	Olsalazine Sodium	Orbifloxacin
Orlistat <i>(Received)</i>	Oxcarbazepine <i>(Received)</i>	Pantoprazole Sodium
Pemoline	Pentamidine Isethionate	Piperonyl Butoxide
Pirbuterol Acetate	Poractant Alpha	Proguanil
Quetiapine Fumarate	Rose Bengal	Salmeterol Xinafoate
Sertraline Hydrochloride	Sodium Phenylbutyrate	Simethicone Powder
Sterile Methotrexate Sodium	Streptozocin	Sulfacytine
Tacrolimus	Terbinafine Hydrochloride	Terconazole
Tiludronate Disodium	Tiopronin	Tranexamic Acid
Trimipramine Maleate	Trovafoxacin Mesylate	Voriconazole
Zinc Tridosium Pentetate		

Noncomplex Actives (Drug Products)

Abacavir Sulfate, Lamivudine, and Zidovudine Tablets	Acarbose Tablets	Acetaminophen, Butalbital, Caffeine, and Codeine Phosphate Capsules
Acetaminophen, Clemastine Fumarate and Pseudoephedrine Hydrochloride Tablets	Acetazolamide Extended-Release Capsules	Albuterol Extended-Release Tablets
Albuterol for Inhalation	Albuterol Inhalation Aerosol	Alendronate Sodium Oral Solution
Alfuzosin Tablets	Allopurinol for Injection	Alprazolam Extended-Release Tablets
Alprostadil Urethral Suppository	Aminopromazine Fumarate and Neomycin Sulfate Tablets	Aminopromazine Fumarate Injection
Aminopromazine Fumarate Tablets	Amlodipine and Benazepril Hydrochloride Capsules	Aminopterin Sodium Tablets
Amphotericin B Injection	Anagrelide Hydrochloride Capsules	Arsenic Trioxide Injection
Atovaquone and Proguanil Hydrochloride Tablets	Atovaquone Tablets	Auranofin Capsules
Azatadine Maleate and Pseudoephedrine Sulfate Extended-Release Tablets	Azelaic Acid Cream	Azithromycin for Injection
Azithromycin Tablets	Baclofen Injection	Balsalazide Disodium Capsules
Beclomethasone Dipropionate Inhalation Aerosol	Beclomethasone Dipropionate Metered-Dose Nasal Suspension	Bentoquatam Topical Suspension
Benzocaine and Cetylpyridinium Chloride Lozenges	Benzocaine and Menthol Lotion	Benzphetamine Hydrochloride Tablets
Bepiridil Tablets	Bicalutamide Tablets	Brompheniramine Maleate, Dextromethorphan Hydrobromide and Pseudoephedrine HCl Oral Solution
Bivalirudin Injection	Budesonide Metered-Dose Inhalation Aerosol	Budesonide Inhalation Aerosol
Bupivacaine and Lidocaine Hydrochlorides Injection	Buprenorphine Hydrochloride Injection	Butalbital and Acetaminophen Capsules
Butalbital and Acetaminophen Tablets	Calcipotriene Topical Solution Cabergoline Tablets	Calcipotriene Cream
Calcipotriene Ointment	Calcitriol Capsules	Calcitriol Oral Solution
Calcium Acetate Capsules	Calfactant Intratracheal Suspension	Calcium Trisodium Pentetate Injection
Carbidopa and Levodopa Extended-Release Tablets	Carbidopa and Levodopa Tablets for Oral Suspension	Carbidopa, Levodopa, and Entacapone Tablets
Carmustine Implant	Carmustine for Injection	Carvedilol Tablets
Cefditoren Pivoxil Tablets	Cefdinir Tablets	Ceftibuten Capsules
Ceftibuten for Oral Suspension	Cetirizine Hydrochloride Oral Solution	Ceftiofur Hydrochloride Oral Suspension
Cetorelix Injection	Cetirizine Hydrochloride Tablets	Cevimeline Hydrochloride Capsules
Choline and Magnesium Salicylates Oral Solution	Chloroxine Cream	Chlorpromazine Hydrochloride Extended-Release Capsules
Ciclopirox Shampoo	Choline and Magnesium Salicylates Tablets	Choline Salicylate Oral Solution
Ciclopirox Topical Gel	Ciclopirox Topical Solution	Ciprofloxacin Hydrochloride and Hydrocortisone Otic Suspension
Cilostazol Tablets <i>(Received)</i>	Cimetidine Oral Solution	Citalopram Hydrobromide Oral Solution
Ciprofloxacin Otic Solution	Cladribine Injection	Citric Acid, Gluconolactone, and Magnesium Carbonate Irrigation
Clonazepam Orally-Disintegrating Tablets	Clemastine Fumarate Syrup	Clobetasol Propionate Gel
Clotrimazole and Betamethasone Dipropionate Lotion	Clorazepate Dipotassium Capsules	Clorazepate Dipotassium Extended-Release Tablets
Colfosceril and Tyloxapol Suspension	Colestipol Hydrochloride Tablets	Conjugated Estrogens and Medroxyprogesterone Acetate Tablets
Compound Undecylenic Acid Cream	Compound Undecylenic Acid Topical Powder	Cyclosporine Modified Oral Solution
Cromolyn Sodium Metered-Dose Nasal Solution	Cyclosporine Modified Capsules	Cysteamine Bitartrate Capsules
Cyclosporine Ointment	Cyclosporine Topical Solution	Cytarabine Liposome Injection
Dantrolene Sodium Capsules <i>(Received)</i>	Dalfopristin and Quinupristin Injection	Dapiprazole for Ophthalmic Solution
Dantrolene Sodium for Injection <i>(Received)</i>	Dantrolene Sodium Oral Suspension	Desirudin for Injection

Noncomplex Actives (Drug Products) (Continued)

Desonide (Received)	Desonide Cream	Dexrazoxane for Injection
Dextroamphetamine Sulfate Extended-Release Capsules	Dextromethorphan Polistirex Extended-Release Oral Suspension	Diazepam Injectable
Diclofenac Sodium Ophthalmic Solution	Didanosine Chewable Tablets (Received)	Diethylpropion Hydrochloride Extended-Release Tablets
Difenoxin and Atropine Tablets	Difloxacin Hydrochloride Tablets	Dihydroergotamine Mesylate Metered Spray
Diltiazem Maleate Extended-Release Tablets	Dinoprostone Vaginal Suppositories	Diphenhydramine Hydrochloride and Acetaminophen Tablets
Divalproex Sodium Delayed-Release Capsules	Dorzolamide and Timolol Ophthalmic Solution	Dorzolamide Ophthalmic Solution
Doxacurium Chloride Injection	Doxepin Hydrochloride Cream	Doxycycline Oral Gel
Econazole Nitrate Cream	Edrophonium Chloride and Atropine Sulfate Injection	Enalaprilat Injection
Enalapril Maleate and Diltiazem Maleate Extended-Release Tablets	Enalapril Maleate and Felodipine Extended-Release Tablets	Entacapone Tablets
Ephedrine Sulfate and Guaifenesin Tablets	Epoprostenol for Injection	Epoprostenol Injection
Esmolol Hydrochloride Injection	Esomeprazole Magnesium Capsules	Estazolam Tablets
Estramustine Phosphate Sodium Capsules	Ethanolamine Oleate Injection	Etomidate Injection
Etidronate Disodium Injection Concentrate	Exemestane Tablets	Famotidine Injection (Received)
Famotidine Orally Disintegrating Tablets	Felbamate Oral Suspension	Felbamate Tablets
Fentanyl Lozenges	Fentanyl Transdermal System	Ferrous Fumarate and Docusate Sodium Extended-Release Capsules
Flavoxate Hydrochloride	Flavoxate Hydrochloride Tablets	Fluconazole Injection
Flunisolide Nasal Spray	Fluconazole Tablets	Flunisolide Inhalation Aerosol
Fluocinolone Acetonide Shampoo	Fluorescein Sodium Ophthalmic Solution	Fluticasone Propionate Inhalation Powder
Fluorometholone Ointment	Fluticasone Propionate Cream (Received)	Fluticasone Propionate Ointment (Received)
Fluticasone Propionate Pressurized Inhaler	Foscarnet Sodium Injection	Fosfomycin for Oral Solution
Gabapentin Oral Solution	Gabapentin Tablets	Gadobenate Dimeglumine Injection
Gallium Nitrate Injection	Galantamine Hydrobromide Tablets	Ganirelix Acetate Injection
Ganciclovir Capsules	Gentamicin Sulfate Oral Solution	Gatifloxacin Injection
Gatifloxacin Tablets	Glipizide Extended-Release Tablets	Gentamicin Sulfate Soluble Powder
Glimepiride Tablets	Granisetron Tablets	Granisetron Injection
Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets	Guaifenesin and Salts of Dextromethorphan and Pseudoephedrine Oral Solution	Guanidine Hydrochloride
Guanidine Hydrochloride Tablets	Halobetasol Propionate Ointment	Halobetasol Propionate Cream
Haloperidol Decanoate Injection	Haloperidol Lactate Injection	Haloperidol Lactate Oral Concentrate
Hydrochlorothiazide Oral Solution Concentrate	Hydrocodone Bitartrate and Acetaminophen Oral Solution	Hydralazine Hydrochloride and Hydrochlorothiazide Capsules
Hydrocodone Bitartrate and Homatropine Methylbromide Syrup	Hydrochlorothiazide Capsules	Hydrocodone Bitartrate and Guaifenesin Oral Solution
Hydrocodone Bitartrate and Aspirin Tablets	Hydrocortisone Butyrate Lotion	Hydrocodone Bitartrate and Homatropine Methylbromide Tablets
Hydrocortisone Acetate Rectal Foam Aerosol	Hydroquinone Lotion	Hydrocortisone Acetate Dental Paste
Hydroflumethiazide and Reserpine Tablets	Hydromorphone Hydrochloride Oral Solution	Ibuprofen Capsules
Ibandronate Sodium Tablets	Idarubicin Hydrochloride Injection	Imipramine Pamoate Capsules
Imiquimod Topical Cream	Ipratropium Bromide Inhalation Aerosol	Ipratropium Bromide Inhalation Solution
Irinotecan Hydrochloride Injection	Isosulfan Blue Injection	Isradipine Extended-Release Tablets
Itraconazole Injection	Itraconazole Oral Solution	Ketoconazole Cream
Ketoconazole Shampoo	Ketoprofen Capsules	Ketoprofen Extended-Release Capsules
Ketotifen Fumarate	Ketotifen Fumarate Ophthalmic Solution	Ketoprofen Tablets
Lactic Acid Lotion	Lamivudine Tablets	Latanoprost Ophthalmic Solution
Levetiracetam Tablets	Levobetaxolol Ophthalmic Suspension	Levocabastine Ophthalmic Suspension
Leucovorin Calcium for Injection	Levomethadyl Acetate Hydrochloride Oral Concentrate	Levofloxacin Solution
Lincomycin Hydrochloride and Spectinomycin Sulfate Soluble Powder	Liothyronine Injection	Lisinopril and Hydrochlorothiazide Tablets

Noncomplex Actives (Drug Products) (Continued)

Lomustine Capsules	Lopinavir Capsules	Lopinavir Solution
Lopinavir and Ritonavir Solution	Loratadine and Pseudoephedrine Sulfate Extended-Release Tablets (Received)	Loratadine Orally-Disintegrating Tablets
Losartan Potassium Tablets	Mesalamine Suppositories	Methacholine Chloride for Inhalation Solution
Mesoridazine Besylate Concentrate	Mefloquine Hydrochloride Tablets	Methoxsalen Softgels
Methadone Hydrochloride Oral Concentrate	Melphalan for Injection	Metaraminol Bitartrate Injection
Methyclothiazide and Deserpidine Tablets	Methocarbamol and Aspirin Tablets	Metipranolol Ophthalmic Solution
Metronidazole Cream	Metronidazole Lotion	Metronidazole Extended-Release Tablets
Methylphenidate Hydrochloride Chewable Tablets	Metronidazole Capsules	Midazolam Hydrochloride Injection
Metronidazole Hydrochloride for Injection	Miconazole Nitrate Topical Aerosol	Mifepristone Tablets
Miglitol Tablets	Milrinone Injection	Misoprostol Dispersion (Received)
Misoprostol Tablets (Received)	Mivacurium in Dextrose Injection	Mivacurium Injection
Moexipril Hydrochloride and Hydrochlorothiazide Tablets	Moexipril Hydrochloride Tablets	Molindone Hydrochloride Oral Solution
Morphine Sulfate for Injection Concentrate	Morphine Sulfate Oral Solution	Morphine Sulfate Oral Solution Concentrate
Morphine Sulfate Tablets	Mycophenolate Mofetil Tablets	Mycophenolate Mofetil Oral Solution
Mycophenolate Mofetil Capsules	Nalbuphine Hydrochloride Injection	Naproxen Extended-Release Tablets
Naphazoline Hydrochloride and Pheniramine Maleate Ophthalmic Solution	Naphazoline Hydrochloride and Pheniramine Maleate Ophthalmic Solution	Nalmefene Hydrochloride Injection
Nateglinide Tablets	Nedocromil Sodium Inhalation Aerosol	Neomycin Sulfate Oral Powder
Nevirapine Oral Suspension (Received)	Nevirapine Tablets (Received)	Nicardipine Hydrochloride Capsules
Nilutamide Tablets	Nimodipine Capsules	Nisoldipine Extended-Release Tablets
Nitroglycerin Solution In Acrylic Adhesive	Nizatidine Tablets	Ofloxacin Injection
Ofloxacin In Dextrose Injection	Ofloxacin Tablet (Received)	Olopatadine Ophthalmic Solution
Olsalazine Sodium Capsules	Ondansetron Oral Solution	Ondansetron Tablets
Orbifloxacin Tablets	Orlistat Capsules (Received)	Orphenadrine Citrate, Aspirin, and Caffeine Tablets
Orphenadrine Citrate Extended Release Tablets	Oxcarbazepine Suspension	Oxcarbazepine Tablets
Oxiconazole Cream	Pancuronium Bromide Injection (Received)	Pantoprazole Sodium Tablets
Pantoprazole Sodium for Injection	Paroxetine Hydrochloride Extended-Release Tablets	Paroxetine Oral Suspension
Pemirolast Potassium Ophthalmic Solution	Pemoline Tablets	Penicillin G Potassium Tablets for Oral Solution
Pentaerythritol Tetranitrate Extended-Release Capsules	Pentaerythritol Tetranitrate Extended-Release Tablets	Pentamidine Isethionate for Inhalation
Pentamidine Isethionate for Injection	Pentazocine Hydrochloride and Acetaminophen Tablets	Permethrin Cream (Received)
Phendimetrazine Tartrate Extended-Release Capsules	Phenobarbital Capsules	Phentermine Resin Complex
Phenylephrine Hydrochloride and Chlorpheniramine Maleate Extended-Release Capsules	Phenylephrine Hydrochloride, Chlorpheniramine Maleate, and Acetaminophen Extended-Release Tablets	Phentermine Resin Complex Capsules
Phosphate Oral Solution	Pilocarpine Hydrochloride Ophthalmic Gel	Pilocarpine Hydrochloride Ophthalmic Ointment
Pilocarpine Hydrochloride Tablets	Piperonyl Butoxide and Pyrethrins Aerosol Foam	Pirbuterol Acetate Inhalation Aerosol
Povacrylate Solution	Poractant Alpha Suspension	Porfimer Sodium for Injection
Povacrylate-Iodine Topical Solution	Povidone-Iodine Gauze	Povidone-Iodine Swabsticks
Povidone-Iodine Topical Aerosol Foam	Povidone-Iodine Vaginal Suppositories	Pramipexole Dihydrochloride Tablets
Prazosin Hydrochloride and Polythiazide Capsules	Prednisolone Sodium Phosphate Oral Solution	Prochlorperazine Maleate Extended-Release Capsules

Noncomplex Actives (Drug Products) (Continued)

Progesterone Capsules	Promethazine Hydrochloride and Codeine Phosphate Oral Solution	Promethazine Hydrochloride and Dextromethorphan Hydrobromide Syrup
Promethazine and Phenylephrine Hydrochlorides and Codeine Phosphate Syrup	Promethazine and Phenylephrine Hydrochlorides Syrup	Propafenone Hydrochloride Tablets
Pseudoephedrine Hydrochloride and Brompheniramine Maleate Extended-Release Tablets	Pseudoephedrine Hydrochloride and Naproxen Sodium Extended-Release Tablets	Pseudoephedrine Hydrochloride, Chlorpheniramine Maleate, and Codeine Phosphate Oral Solution
Pseudoephedrine Hydrochloride, Guai-fenesin, and Codeine Phosphate Oral Solution	Pseudoephedrine Sulfate and Dexbrompheniramine Maleate Extended-Release Tablets	Pseudoephedrine Sulfate and Dexbrompheniramine Maleate Oral Solution
Pseudoephedrine Sulfate, Dexbrompheniramine Maleate, and Acetaminophen Extended-Release Tablets	Pyrilamine Maleate Injection	Quinidine Sulfate Injection
		Ramipril Capsules
Ranitidine Capsules	Rauwolfia Serpentina and Endroflumethiazide Tablets	Reserpine and Polythiazide Tablets
Rimantadine Hydrochloride Oral Solution	Risperidone Oral Solution	Risperidone Orally Disintegrating Tablets
Risperidone Tablets	Rivastigmine Tartrate Capsules	Rivastigmine Tartrate Oral Solution
Rocuronium Bromide Injection	Ropinirole Hydrochloride Tablets	Rose Bengal Ophthalmic Solution
Rosiglitazone Maleate Tablets	Salicylic Acid and Sulfur Cleansing Lotion	Salicylic Acid and Sulfur Lotion
Salicylic Acid and Sulfur Shampoo	Salicylic Acid Cream	Salicylic Acid Ointment
Salmeterol Inhalation Aerosol	Salmeterol Xinafoate Inhalation Powder	Scopolamine Transdermal System
Selegiline Hydrochloride Capsules	Serpacwa Topical Cream	Sertraline Hydrochloride Oral Solution
Sibutramine Hydrochloride Capsules	Sodium Bicarbonate and Sodium Citrate for Oral Solution	Sodium Bicarbonate, Sodium Citrate, and Sodium Tartrate for Oral Suspension
Sodium Chlorophyllin Copper Complex Tablets	Sodium Iodide Injection	Sodium Phenylbutyrate Oral Powder
Sodium Phenylbutyrate Tablets	Sodium Phosphates for Oral Suspension	Sodium Phosphates Tablets
Sodium Salicylate and Sulfur Shampoo	Sterile Talc Aerosol	Streptozocin for Injection
Sucralfate Oral Suspension	Sulconazole Nitrate Cream	Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution
Sulfacetamide Sodium and Fluorometholone Ophthalmic Suspension	Sulfacytine Tablets	Sulfanilamide Vaginal Cream
Sulfasalazine Oral Suspension	Sumatriptan Tablets	Sulisobenzene Lotion
Sumatriptan Injection	Tacrolimus Capsules	Tacrolimus Ointment
Tacrolimus Injection	Tamsulosin Hydrochloride Capsules	Technetium Tc 99M Teboroxime Injection
Tenofovir Disoproxil Fumarate Tablets	Terbinafine Hydrochloride Cream	Terbinafine Tablets
Terbinafine Topical Solution	Terconazole Vaginal Cream	Terconazole Vaginal Suppositories
Testosterone Transdermal System	Tetracycline Hydrochloride Periodontal Fiber	Theophylline Extended-Release Tablets
Tioconazole Vaginal Ointment	Tiopronin Tablets	Tolnaftate Topical Aerosol Solution
Topiramate Capsules	Topiramate Tablets	Toremide Injection
Toremide Tablets	Trandolapril and Verapamil Hydrochloride Extended-Release Tablets	Trandolapril Tablets
Tranexamic Acid Injection	Tranlycypromine Sulfate	Tranlycypromine Sulfate Tablets
Tretinoin Capsules	Tretinoin Microsphere Gel	Triamcinolone Acetonide Metered-Dose Nasal Suspension
Trifluridine Ophthalmic Solution	Trimetrexate for Injection	Trimipramine Maleate Capsules
Tripolidine and Pseudoephedrine Hydrochlorides and Codeine Phosphate Syrup	Trolamine Salicylate Cream	Trolamine Salicylate Gel
Trolamine Salicylate Topical Emulsion	Trovaflaxacin Injection	Trovaflaxacin Mesylate for Injection
Undecylenic Acid Topical Foam Aerosol	Unoprostone Isopropyl Ophthalmic Solution	Urea Cream
Vecuronium Bromide for Injection	Venlafaxine Extended-Release Capsules	Venlafaxine Tablets
Verapamil Hydrochloride Capsules	Verapamil Hydrochloride Extended-Release Capsules	Voriconazole Injection
Voriconazole Oral Suspension	Voriconazole Tablets	Yttrium Y-90 Chloride Solution
Yttrium Y-90 Glass Microspheres	Yttrium Y-90 Microspheres Injection	Ziprasidone Hydrochloride Capsules
Zidovudine and Lamivudine Tablets	Zinc Acetate Capsules	Zoledronic Acid for Injection
Zinc Tridosium Pentetate Injection		

Excipients

Acetone Sodium Bisulfite	Acetylated Monoglycerides	N-Acetyl-L- Methionine
Aconitic Acid (Achilleic Acid)	Acrylic Acid-Octyl Acrylate Copolymer	Albumin Colloidal
Aliphatic Polyesters	Aluminum Ammonium Sulfate	Aluminum Hydroxide
Aluminum Lactate	Aluminum Oxide	Aluminum Ammonium Sulfate
Aluminum Potassium Sulfate	Aluminum Silicate	Aluminum Sodium Sulfate
Aluminum Stearate	Allantoin-Sodium Pyrrolidone Carboxylate	Ammonium Bicarbonate
Ammonium Calcium Alginate	Ammonium Phosphate	L-Ascorbyl Stearate
L-Asparagine	Batylalcohol Monostearate	Beeswax, Synthetic
Benzododecinium Bromide	Benzyl Chloride	Benzyl Nicotinate
Brominated Vegetable Oil	Butadiene-Styrene Rubber	Beta Naphthol
Butylene Glycol	Butylphthalyl Butylglycolate	Butylated Hydromethylphenol
Calcium Alginate	Calcium Alginate and Ammonium Alginate	Calcium Acid Pyrophosphate
Calcium Chloride Solution	Calcium Glycerophosphate <i>(Received)</i>	Calcium Bromide
Calcium Phosphaite Dibasic, Monohydrate	Calcium Phosphate Monobasic	Calcium Phosphate Dibasic, Anhydrous
Calcium Pyrophosphate	Calcium Sorbate	Calcium Propionate
Calcium Sulfate Dihydrate	Calcium Sulfate, Anhydrous	Calcium Stearoyl Lactylate
Calteridol Calcium	Canola Oil	Caldiamide Sodium
Caprylic/Capric Diglyceril Succinate	Carbon	Capric Acid
Carboxymethylamylopectin Sodium	Carboxymethylcellulose Potassium	Carboxymethyl Starch
Cetostearyl Isononanoate	Cholic Acid	Cinnamaldehyde
Chlorodifluoroethane	Cocamide Diethanolamine	Cocamide Oxide
Coconut Oil Hydrogenated <i>(Received)</i>	Cocoyl Caprylocaprate	Coconut Oil
Crystal Gum	Cutina	Copper Sulfate
L-Cysteine Monohydrochloride	Dammar Gum	Cystine
Decanoic Acid	Decyl Oleate	Dehydroacetic Acid
Desoxycholic Acid	Dextrin Palmitate	Dextrins Modified
Diacetyl Tartaric Acid Esters Of Mono- and Diglycerides	Dicetyl Phosphate	Dichlorofluoromethane
Diethylene Glycol Monopalmitostearate	Diethyl Sebacate	Difluoroethane
Diglycol Stearate	Diisobutyl Adipate	Diisopropyl Adipate
Diisopropylbenzothiazyl-2-Sulfenamide	Dilauryl Thiodipropionate	Dimethyl Dicarboxylate
Dimyristoyl Lecithin	Dimyristoyl Phosphatidylglycerol	Diocetyl Sodium Sulfosuccinate
Dipropylene Glycol	Disodium Edisylate	Disodium Guanylate
Disodium Inosinate	Disodium Monooleamide Sulfasuccinate	Docusate Sodium/Sodium Benzoate
Erythorbic Acid	Erythrosine	Ethoxylated Mono- and Diglycerides
Ethoxyquin	Ethyl Hexanediol	Ethyl Linoleate
Ethyl Maltol	Ethylene Dichloride	Ethylene Glycol Monopalmitostearate
Ethylurea	Ferric Ammonium Citrate	Ferric Citrate
Ferric Oxide, Brown	Ferric Phosphate	Ferric Pyrophosphate
Ferrous Citrate	Ferrous Glycinate	Ferrous Lactate
Fluorochlorohydrocarbons	Formic Acid	Furcelleran
Gamma-Cyclodextrin	Gentistic Acid	Geraniol
L-Glutamic Acid	Glutamic Acid Hydrochloride	Gluten
Glycerol Ester of Gum Rosin (Ester Gum)	Glyceryl Laurate	Glyceryl Palmitate
Glyceryl Ricinoleate	Glyceryl Tristearate	Glycine Hydrochloride
Glycofurool	Glycol Stearate	Heptafluoropropane
Heptylparaben	Hexadecyl Isostearate	Hexane
Hexanetriol(-1,2,6-)	Hydrocarbon Gel	Hydrogenated Starch Hydrolysate
Hydroxyethylmethylcellulose	Hydroxylated Lecithin	Hydroxypropyl Beta Cyclodextrin
Indigotine	Inositol	Iron Carbonyl
Iron Subcarbonate	Isobutylated-Isoprene Copolymer	Isooctylacrylate
Isopropyl Isostearate	Isopropyl Stearate	Isostearic Acid
Isostearyl Alcohol	Lactobionic Acid	Lactose Ferrin, Bovine
Lactylated Fatty Acid Esters of Glycerol and Propylene Glycol	Lactylic Esters of Fatty Acids	Lanolin Anhydrous
Lanolin Alcohols, Acetylated	Lanolin (Wool Fat), Hydrogenated	Lanolin Hydrous
Lauramine Oxide	Lauric Acid	Lauric Diethanolamide

Excipients (Continued)

Lauric Myristic Diethanolamide	Lavender Oil	Lecithin, Hydroxylated
L-Leucine	Linoleic Acid	Macrogol Lauryl Ether
Macrogol Oleate	Macrogol Sorbitan Tristearate	Macrogol Stearyl Ether
Macrogolglycerol Cocoates	Macrogolglycerol Triisostearate	Magnesium Aluminum Silicate Hydrate
Magnesium Aspartate	Magnesium Aspartame Dihydrate	Magnesium Phosphate, Diabasic, Trihydrate
Magnesium Phosphate Tribasic	Magnesium Tartrate	Maltitol Syrup
Maltol Isobutyrate	Malt Syrup	Manganese Chloride
Manganese Citrate	Manganese Glycerophosphate	Manganese Hypophosphite
D-Mannose	Medical Antifoam Emulsion C	Medronate Disodium
Medronic Acid	Methyl Chloride	Methylchloroisothiazolinone
Methyl Hydroxyethyl Cellulose	Methylisothiazolinone	N-Methylpyrrolidone (Received)
Microcrystalline Cellulose, Silicified (Received)	Mineral Spirits	Monoisostearyl Glyceryl Ester
Monopotassium Glutamate Monohydrate	Monosodium Citrate	Mullein Leaf
Myristyl Gamma-Picolinium Chloride	Myristyl Lactate	N,N-Bis(2-Hydroxyethyl) Stearamide
Naphtha	Non-Pareil Seeds	Nutmeg Oil
Octanoic Acid	Oxystearin	Palm Kernel Oil
Palm Oil	Pentasodium Triphosphate	Pentetate Calcium Trisodium
Pentetate Pentasodium	Phenprobamate	Phenylmercuric Acetate
Phenylmercuric Nitrate	Pine Oil	Polacrillin
Polyacrylate Dispersion 30 Percent (Received)	Polydextrose	Polydextrose Solution
Polyglycerol Esters of Fatty Acids	Polyglycerol Polyricinoleic Acid	Polyoxyethylene Castor Oil (USP has 35)
Polyoxyl Stearate (USP has 40)	Polypropylene Oleate	Polyvinyl Acetate (Received)
Polyvinylacetal	Polyvinylacetal Diethylanoacetate	Polyvinylpyrrolidone
Polypropylene Stearyl Ether	Polyvinylpyrrolidone Ethylcellulose	Polysorbate 65
Potassium Acid Tartrate	Potassium Bromate	Potassium Carbonate Solution
Potassium Dichloroisocyanurate	Potassium Gibberellate	Potassium Glycerophosphate
Potassium Iodate	Potassium Nitrite	Potassium Phosphate
Potassium Phosphate Tribasic	Potassium Polymetaphosphate	Potassium Pyrophosphate
Potassium Stearate	Potassium Sulfate	Potassium Sulfite
Potassium Tripolyphosphate	Propylene Glycol Diacetate	Propylene Glycol Mono- and Diesters
Propyl Propionate	Purified Polyoxyl 35 Castor Oil (Received)	Rapeseed Oil, Hydrogenated
Rapeseed Oil, Superglycerinated	Rice Bran Wax	Rosin
Silicone	Sodium Acid Pyrophosphate	Sodium Aluminosilicate
Sodium Aluminum Phosphate Acidic	Sodium Aluminum Phosphate Basic	Sodium Aspartate
Sodium Bisulfate	Sodium Bisulfite	Sodium Carbonate Hydrate
Sodium Carboxymethyl Betaglucon	Sodium Caseinate	Sodium Chlorate
Sodium Citrate, Dibasic	Sodium Citrate, Monobasic	Sodium Dehydroacetate
Sodium Diacetate	Sodium Erythorbate	Sodium Ferric Pyrophosphate
Sodium Ferrocyanide	Sodium Hypophosphite	Sodium Laureth Sulfate
Sodium Lauroyl Sarcosinate	Sodium Lauryl Sulfoacetate	Sodium Magnesium Aluminosilicate
Sodium Magnesium Silicate	Sodium Malate	Sodium Metaphosphate, Insoluble
Sodium Metasilicate	Sodium Methylate	Sodium Polyphosphates Glassy
Sodium Potassium Tripolyphosphate	Sodium Pyrophosphate	Sodium Pyrrolidone Carboxylate
Sodium Sesquicarbonate	Sodium Sesquinoate	Sodium Stearoyl Lactylate
Sodium Thiomalate	Sodium Trimetaphosphate	Sodium Trioleate
Sodium Tripolyphosphate	Soy Polysaccharides	Stannous Chloride
Stannous Tartrate	Starch, Pregelatinized Corn	Starch, Pregelatinized Tapioca
Stearalkonium Chloride	Stearyl Citrate	Stearyl Monoglyceridyl Citrate
Succinylated Monoglycerides	Sucrose Acetate Isobutyrate	Sucrose Fatty Acid Esters
Sucrose Stearate	Sucrose Syrup	Sugar Fruit Fine
Sulfobutyl Ether Beta Cyclodextran	Tallow	Tallow Glycerides
Tallow Oil	Tetrafluoroethane	Thioglycerol
Thyme Oil	Tribehenin	Triceteareth-4 Phosphate

Excipients (Continued)

Trichloroethylene	Trimyristin	Trisodium Citrate
Trolamine Lauryl Sulfate	Vegetable Oil	Wheat Flour
Wheat Gluten	Wheat Germ Oil	Whey

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The Role of Container–Closure Systems in Stability Testing For Climate Zone IV*

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ABSTRACT The authors suggest that designation of long-term stability test conditions must include the effect of barrier packaging on the atmosphere inside the package. In December 2004, the Association of South East Asian Nations (ASEAN) proposed to the World Health Organization (WHO) that the standard for long-term stability testing for markets in Climate Zone IV be changed from 30 °C, 65% relative humidity (RH) to 30 °C, 75% RH. The argument for this proposal was based on the effect of absolute humidity on drug products. It did not take into account the effect of barrier packaging on control of the absolute humidity inside the package. The authors stipulate that selection of stability test conditions must include consideration of package permeation, storage temperature, and the permeation driving force, i.e., partial pressure for water vapor. The authors show that for challenge of the packaged drug product, relative humidities lower than 75% at 30 °C would adequately represent the ASEAN countries' Climate Zone average condition of 27 °C, 79% RH. Laboratory testing is advised.

USP Dictionary of USAN and International Drug Names 2005 USP DICTIONARY SUPPLEMENT 6

IMPORTANT—Save this Supplement. This and all supplements appearing in *PF* are needed to keep the 2005 edition of the USP Dictionary (USPD) up-to-date. The cumulative contents of the supplements to the current (2005) edition will be included in the next complete edition of the Dictionary.

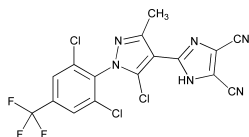
Revisions of United States Adopted Names (USAN)

The following are revisions of existing United States Adopted Names (USAN) and other names.

Famproniil

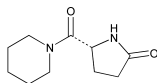
Change the chemical information and structure to read:

$C_{16}H_6Cl_3F_3N_6$. 445.61. 2-{5-Chloro-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-3-methyl-1*H*-pyrazol-4-yl]-1*H*-imidazole-4,5-dicarbonitrile. *CAS-134183-95-2*. INN.



Fasoracetam

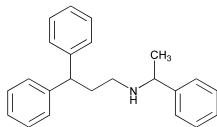
Change the chemical structure to read:



Fendiline

Change the chemical information and structure to read:

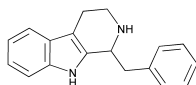
$C_{23}H_{25}N$. 315.45. *N*-(3,3-Diphenylpropyl)- α -methylbenzylamine. *CAS-13042-18-7*. INN; MI.



Fenharmane

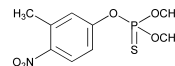
Change the chemical information and structure to read:

$C_{18}H_{18}N_2$. 262.35. 1-Benzyl-2,3,4,9-tetrahydro-1*H*-pyrido[4,3-*b*]indole. *CAS-3851-30-7*. INN.



Fenitrothion

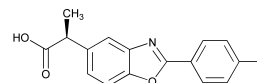
Change the chemical structure to read:



Flunoxaprofen

Change the chemical information and structure to read:

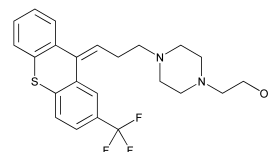
$C_{16}H_{12}FNO_3$. 285.27. (*S*)-(+)-2-(*p*-Fluorophenyl)- α -methyl-5-benzoxazoleacetic acid. *CAS-66934-18-7*. INN; MI.



Flupentixol

Change the chemical information and structure to read:

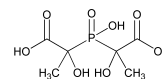
$C_{23}H_{25}F_3N_2OS$. 434.52. (*Z*)-2-Trifluoromethyl-9-[3-[4-(2-hydroxyethyl)piperazin-1-yl]propylidene]thioxanthene. *CAS-2709-56-0*. INN; BAN; DFC; MI. [Name previously used: *Flupenthixol*.] \rightleftharpoons *N*-7009; *LC* 44.



Foscolic Acid

Change the chemical formula and structure to read:

$C_6H_{11}O_8P$.



Mitomycin

Change the chemical structure to read:

