

PHARMACOPEIAL FORUM

34

NUMBER 4

BIMONTHLY: July-August 2008

Featured in This Issue

USP has identified the following content area in the July-August 2008 issue of *Pharmacopeial Forum* as noteworthy for the pharmaceutical industry worldwide.

- Interim Revision Announcements Pertaining to *USP 31-NF 26* (official June 1, 2008)
 - Diclofenac Potassium Tablets
 - Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets
 - Fludeoxyglucose F 18 Injection
 - Valproate Sodium Injection
- Proposed Revisions to General Chapters <1> Injections and <1090> In vivo Bioequivalence Guidances
- Stimuli Articles
 - Use of Scanning Electron Microscopy in the Authentication of Botanicals
 - The Inhalation Ad Hoc Advisory Panel for the USP Performance Tests of Inhalation Dosage Forms

A detailed listing of the Table of Contents of the July-August issue of *Pharmacopeial 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
Darrell Abernethy Chief Science Officer	dra@usp.org	(301) 816-8184	
Clydewyn M. Anthony, Ph.D., Scientist	cma@usp.org	(301) 816-8139	Monograph Development— Cough, Cold, and Analgesics (MD-CCA)
Fouad Atouf, Ph.D., Senior Scientific Associate	fa@usp.org	(301) 816-8365	B&B Cell, Gene, and Tissue Therapies (BB CGT)
Shawn C. Becker, M.S., B.S.N., R.N., Director, Patient Safety Initiatives	scb@usp.org	(301) 816-8216	
Daniel K. Bempong, Ph.D., Senior Scientist	dkb@usp.org	(301) 816-8143	Pulmonary and Steroids (MD-PS)
Kristie Bowman, Senior Scientific Associate	kxb@usp.org	(301) 816-8462	Food Ingredients (FI)
William E. Brown, Senior Scientist	web@usp.org	(301) 816-8380	Biopharmaceutics (BPC); Pharmaceutical Dosage Forms (PDF)
Damián A. Cairatti, Senior Scientist	dac@usp.org	(301) 816-8307	USP–NF Spanish Edition
Larry N. Callahan, Ph.D., Senior Scientist	lnc@usp.org	(301) 816-8385	B&B Proteins and Polysaccha- rides (BB PP)
Todd L. Cecil, Ph.D., Vice President, Compendial Sciences	tlc@usp.org	(301) 816-8234	
Diane Cousins, R.Ph., Vice President, Healthcare Quality and Information	ddc@usp.org	(301) 816-8215	
Behnam Davani, Ph.D., Senior Scientist	bd@usp.org	(301) 816-8394	Monograph Development— Antivirals and Antimicrobials (MD-AA)
Anthony DeStefano, Vice President, General Chapters	ajd@usp.org	(301) 998-6303	
Ian F. DeVeau, Ph.D., Director, Veterinary Drugs and Radiopharmaceuticals	ifd@usp.org	(301) 816-8178	Veterinary Drugs (VET)
Shawn F. Dressman, Ph.D., Director, Reference Standards Evaluation	sfd@usp.org	(301) 816-8261	Reference Standards (RS)
Lawrence Evans III, Ph.D., M.P.H., Senior Scientist	le@usp.org	(301) 816-8389	Dietary Supplements—Non- Botanicals (DSN)
Gabriel I. Giancaspro, Ph.D., Director, Dietary Supplements	gig@usp.org	(301) 816-8343	
Brian D. Gilbert, Ph.D., Scientist	bg@usp.org	(301) 816-8223	
Elena Gonikberg, Ph.D., Senior Scientist	eg@usp.org	(301) 816-8251	Monograph Development— Gastrointestinal, Renal, and Endocrine (MD-GRE)
James Griffiths, Vice President, Food and Dietary Supplement Standards	jg@usp.org	(301) 998-6811	

STAFF DIRECTORY (continued)

STAFF	E-MAIL	PHONE	ASSIGNMENT
Antonio Hernandez-Cardoso, Scientist, Latin American Specialist	ahc@usp.org	(301) 816-8308	USP Spanish Edition; General Chapters (GC)
Desmond G. Hunt, Ph.D., Scientist	dgh@usp.org	(301) 816-8341	Packaging and Storage (P&S); Parenteral Products— Industrial (PPI)
Ping Jin, Ph.D., Senior Scientific Associate	pj@usp.org	(301) 998-6827	Dietary Supplements— Performance Standards (DS-PS)
Jymeann King, R.Ph., Drug Information Specialist	jk@usp.org	(301) 816-8507	Drug Information
Robert Lafaver, Scientist	rhl@usp.org	(301) 816-8335	Excipient Monographs 1 (EM1); Excipient General Chapters (EGC)
Angela G. Long, Vice President, Volunteer and Organizational Affairs and Executive Secretariat	agl@usp.org	(301) 816-8382	
Victor Xiaobin Lu, Ph.D., Senior Scientist	vxl@usp.org	(301) 816-8336	B&B Vaccines and Virology (BB-VV)
Feiwen Mao, Scientist	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); Reagents
Marcia D. Mayfield, Manager, Monograph Development	mxm@usp.org	(301) 816-8358	
Jeff Moore, Ph.D., Senior Scientific Associate	jm@usp.org	(301) 816-8288	Food Ingredients (FI)
Kevin Moore, Ph.D., Scientist	ktm@usp.org	(301) 816-8369	Harmonization; Monograph Improvement
Tina S. Morris, Ph.D., Director, Biologics and Biotechnology	tsm@usp.org	(301) 816-8397	
Amy Neal, DVM, Senior Scientist	an@usp.org	(301) 998-6786	Veterinary Medicine Information (VMI)
Claudia C. Okeke, Ph.D., Scientific Fellow, Patient Safety	cco@usp.org	(301) 816-8243	Sterile Compounding (SCC)
Horacio Pappa, Ph.D., Senior Scientist and Latin American Liaison	hp@usp.org	(301) 816-8319	General Chapters (GC); Statistics (STAT)
Denise Penn, R.Ph., Senior Drug Information Specialist	dsp@usp.org	(301) 816-8392	Drug Information
Deborah G. Perfetto, Pharm.D., Director, Healthcare Information	dgp@usp.org	(301) 816-8317	
Morgan Puderbaugh, Scientific Associate	mxp@usp.org	(301) 998-6833	
Sujatha Ramakrishna, Ph.D., Scientist	sxr@usp.org	(301) 816-8349	Monograph Development— Cardiovascular (MD-CV)
Hariram Ramanathan, Scientific Associate	hr@usp.org	(301) 816-8313	
Ravi Ravichandran, Ph.D., Senior Scientist	rr@usp.org	(301) 816-8330	Monograph Development— Psychiatrics and Psychoactives (MD-PP)

STAFF DIRECTORY (continued)

STAFF	E-MAIL	PHONE	ASSIGNMENT
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., Director, Small Molecules and Monograph Acquisition	kar@usp.org	(301) 816-8379	
Leonel Santos, Ph.D., Senior Scientist	lxs@usp.org	(301) 816-8168	International Health (IH)
Dandapantula Sarma, Ph.D., Senior Scientist	dns@usp.org	(301) 816-8354	Dietary Supplements— Information (DSI)
Rick Schnatz, Pharm.D., Manager	rxs@usp.org	(301) 816-8526	Compounding Pharmacy (CRX)
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)
Catherine M. Sheehan, Director, Excipients and Food Ingredients	cxs@usp.org	(301) 816-8262	Food Additives (FA)
Tom Sigambris, M.S., Scientist	tzs@usp.org	(301) 998-6789	
Nora R. Suarez, Scientific Associate	nrs@usp.org	(301) 816-8326	
Anita Y. Szajek, Ph.D., Senior Scientist	aey@usp.org	(301) 816-8325	B&B Blood and Blood Products (BB BBP)
Radhakrishna S. Tirumalai, Ph.D., Senior Scientist	rst@usp.org	(301) 816-8339	General Toxicity and Medical Device Biocompatibility (GTMDB); Microbiology and Sterility Assurance (MSA)
Yoshiyuki Tokiwa, Ph.D., Senior Scientist	yt@usp.org	(301) 816-8321	Dietary Supplements— General Chapters (DS-GC)
Domenick Vicchio, Senior Scientist	dvw@usp.org	(301) 998-6828	
Hong Wang, Ph.D., Scientist	hw@usp.org	(301) 816-8351	Excipient Monographs 2 (EM2); Excipient General Chapters (EGC)
Andrzej Wilk, Ph.D., Sr. Scientist	aw@usp.org	(301) 816-8305	Nomenclature (NOM)
Ahalya Wise, Scientist	aww@usp.org	(301) 816-8607	Monograph Development— Antibiotics (MD-ANT)
Kahkashan Zaidi, Ph.D., Senior Scientist	kxz@usp.org	(301) 816-8269	Aerosols (AER); General Chapters (GC)

USE OF USP WEBSITE. USP is relocating information formerly published in *PF* to the www.usp.org website. USP is undertaking this initiative to assure that all interested parties have access to this information. USP understands the information it publishes is critical to industry operations and needs to be broadly communicated to stakeholders in a timely manner. Because the website is available to everyone and is routinely maintained, it is the ideal vehicle for USP to use to achieve this goal.

The following information, previously published in the *Policies and Announcements* section of the *Pharmacoepial Forum*, is now accessible on USP's website.

- IRA Commentary
- Compendial Notices
- Pharmacoepial Education Courses

Other important information that resides on the USP website includes:

- Rules and Procedures of the Council of Experts
- Revision Bulletins
- Postponements
- Intent to Revise Letters
- Explanatory Notes and Announcements
- Errata Announcements
- *Stimuli to the Revision Process* Articles
- Reference Standards Catalog

The USP intends to continue this effort and is targeting the following information to be posted only to the USP website in the near future:

- Reference Standards Abeyance List

- High Priority Monograph List

USP encourages stakeholders to sign up for the *Compendial Notices* e-mail service in order to receive notices of new postings to the USP website. To sign up for this service, go to <http://www.usp.org/support/products/uspNewslettersRequest.html?promo=compendial>.

RESIDUAL SOLVENTS: GENERAL NOTICES AND GENERAL CHAPTER <467>—OFFICIAL JULY 1, 2008. The USP Residual Solvent requirements in the both the *General Notices* and General Chapter <467> become official July 1, 2008. As a result 1) the title of General Chapter <467> is now *Residual Solvents* instead of *Organic Volatile Impurities*; 2) the section in <467> titled *Other Analytical Procedures* is now obsolete; and 3) references to *Organic Volatile Impurities* are deleted from monographs. Please direct any questions to Horacio Pappa, Ph.D., Senior Scientist (301-816-8319 or hp@usp.org).

PHARMACOPEIAL FORUM PUBLIC REVIEW AND COMMENT PERIOD DEADLINES. The USP welcomes and encourages interested parties to submit comments and data regarding potential, proposed, or adopted (official) standards. In accordance with the Rules and Procedures of the 2005–2010 Council of Experts, USP has implemented a 90-day comment period by providing a deadline for each issue of *PF* unless otherwise stated in the individual *Briefing*. The listing of comment period deadlines and the targeted official publications are listed below.

Pharmacoepial Forum	Comment Deadline	Targeted Official Publication	Publication Date	Official Date
<i>PF</i> 34(2)	June 15, 2008	<i>USP 32–NF 27</i>	February 2009	August 2009
<i>PF</i> 34(3)	August 15, 2008	<i>1st Supplement</i>		
<i>PF</i> 34(4)	October 15, 2008	<i>USP 32–NF 27</i>	June 2009	December 2009
<i>PF</i> 34(5)	December 15, 2008	<i>2nd Supplement</i>		
<i>PF</i> 34(6)	February 15, 2009	<i>USP 33–NF 28</i>	November 2009	May 2010
<i>PF</i> 35(1)	April 15, 2009			

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 *IRAs* appearing in *PF* Numbers 5 and 6 of each vol-

ume will not appear until *Supplement 1*. See table on the next page. 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 table below outlines the publications and their release and official dates, and the book or *Supplement* that supersedes them.

Publication Schedules

Publication	Release Date	Official Date	Superseded by
<i>USP 31–NF 26</i>	Nov. 1, 2007	May 1, 2008	<i>1st Supplement to USP 31–NF 26</i>
<i>IRA [PF 34(1)]</i>	Jan. 1, 2008	Feb. 1, 2008	<i>2nd Supplement to USP 31–NF 26</i>
<i>1st Supplement to USP 31–NF 26</i>	Feb. 1, 2008	Aug. 1, 2008	<i>2nd Supplement to USP 31–NF 26</i>
<i>IRA [PF 34(2)]</i>	Mar. 1, 2008	Apr. 1, 2008	<i>2nd Supplement to USP 31–NF 26</i>
<i>IRA [PF 34(3)]</i>	May 1, 2008	June 1, 2008	<i>USP 32–NF 27</i>
<i>2nd Supplement to USP 31–NF 26</i>	June 1, 2008	Dec. 1, 2008*	<i>USP 32–NF 27</i>
<i>IRA [PF 34(4)]</i>	July 1, 2008	Aug. 1, 2008	<i>1st Supplement to USP 32–NF 27</i>
<i>IRA [PF 34(5)]</i>	Sept. 1, 2008*	Oct. 1, 2008*	<i>1st Supplement to USP 32–NF 27</i>
<i>IRA [PF 34(6)]</i>	Nov. 1, 2008*	Dec. 1, 2008*	<i>2nd Supplement to USP 32–NF 27</i>

* Tentative.

PRIORITY NEW MONOGRAPH ITEMS. 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 the monograph proposal. Received monographs are removed from this list upon publication in *Pharmacopeial Forum* or when posted in the Pending Monographs section of the USP website (<http://www.usp.org/standards/pending/>).

(This list has been updated as of April 22, 2008.) For the most current list, please consult the Priority New Monograph Items List posted at <http://www.usp.org/USPNF/submitMonograph/newMon.html>.

Monograph sponsors should consult *USP's Guideline for Submitting Requests for Revision to the USP–NF* posted at <http://www.usp.org/USPNF/submitMonograph/subGuide.html>.

For additional information, contact Karen A. Russo, Ph.D., kar@usp.org.

Small Molecules (Drug Substances)—As of April 22, 2008

1. Allopurinol Sodium	2. Aminopropazine Fumarate	3. Aminopterin Sodium
4. Anagrelide Hydrochloride <i>(Received)</i>	5. Arsenic Trioxide	6. Auranfoin
7. Azelaic Acid <i>(Received)</i>	8. Balsalazide Disodium	9. Bentoquatam
10. Benzphetamine Hydrochloride	11. Bivalirudin <i>(Received)</i>	12. Calcipotriene
13. Calcium Trisodium Pentetate	14. Calfactant	15. Candesartan Cilexetil <i>(Received)</i>
16. Carmustine <i>(Received)</i>	17. Cefditoren Pivoxil <i>(Received)</i>	18. Cefibuten
19. Cefiofur Hydrochloride <i>(Received)</i>	20. Cetorelix	21. Cevimeline
22. Chloroxine	23. Choline Salicylate	24. Cysteamine Bitartrate
25. Cytarabine Liposome	26. Dalfopristin	27. Dapirazole Hydrochloride
28. Desirudin	29. Desonide <i>(Received)</i>	30. Dexrazoxane
31. Dextromethorphan Polistirex	32. Difenoxin Hydrochloride	33. Difloxacin Hydrochloride
34. Entacapone <i>(Received)</i>	35. Epoprostenol Sodium <i>(Received)</i>	36. Erythromycin Phosphate
37. Erythromycin Thiocyanate	38. Esmolol Hydrochloride <i>(Received)</i>	39. Estazolam

Small Molecules (Drug Substances)—As of April 22, 2008 (Continued)

40. Estramustine Phosphate Sodium	41. Ethanolamine Oleate	42. Etomidate <i>(Received)</i>
43. Etoposide Phosphate	44. Exemestane	45. Famciclovir
46. Felbamate	47. Fluoromethane F 18	48. Fosfomycin Tromethamine <i>(Received)</i>
49. Gadobenate Dimeglumine	50. Gadopentetic Acid	51. Gallium Nitrate
52. Ganirelix	53. Glyceryl Aminobenzoate	54. Guanidine Hydrochloride
55. Halobetasol Propionate <i>(Received)</i>	56. Haloperidol Decanoate <i>(Received)</i>	57. Hydrocodone Polistirex
58. Ibandronate Sodium	59. Imipramine Pamoate	60. Imiquimod
61. Irinotecan Hydrochloride <i>(Received)</i>	62. Isosulfan Blue	63. Itraconazole <i>(Received)</i>
64. Latanoprost <i>(Received)</i>	65. Lomustine <i>(Received)</i>	66. Lopinavir
67. Metipranolol Hydrochloride	68. Midazolam <i>(Received)</i>	69. Miglitol
70. Milrinone Lactate	71. Misoprostol <i>(Received)</i>	72. Moexipril Hydrochloride
73. Nalbuphine Hydrochloride	74. Nalmefene Hydrochloride	75. Nateglinide <i>(Received)</i>
76. Nedocromil Sodium	77. Nicardipine Hydrochloride	78. Nilutamide
79. Nisoldipine	80. Olsalazine Sodium <i>(Received)</i>	81. Orlistat <i>(Received)</i>
82. Oxcarbazepine <i>(Received)</i>	83. Oxiconazole Nitrate	84. Pemirolast Potassium
85. Pentamidine Isethionate <i>(Received)</i>	86. Pioglitazone Hydrochloride	87. Piperonyl Butoxide
88. Pirbuterol Acetate	89. Poractant Alpha	90. Porfimer Sodium
91. Pramiprexole Dihydrochloride	92. Quetiapine Fumarate <i>(Received)</i>	93. Ranitidine
94. Rivastigmine Tartrate <i>(Received)</i>	95. Ropinirole Hydrochloride	96. Rose Bengal Disodium
97. Rosiglitazone Maleate	98. Salmeterol Xinafoate <i>(Received)</i>	99. Sertraline Hydrochloride <i>(Received)</i>
100. Sibutramine Hydrochloride <i>(Received)</i>	101. Sodium Phenylbutyrate	102. Sodium Phosphates
103. Spectinomycin Sulfate	104. Streptozocin	105. Tacrolimus <i>(Received)</i>
106. Tenofovir Disoproxil Fumarate <i>(Received)</i>	107. Terconazole <i>(Received)</i>	108. Tiludronate Disodium
109. Tiopronin	110. Tranexamic Acid <i>(Received)</i>	111. Tranylcypromine Sulfate <i>(Received)</i>
112. Trimetrexate Glucuronate	113. Venlafaxine Hydrochloride <i>(Received)</i>	114. Voriconazole <i>(Received)</i>
115. Zaleplon	116. Zinc Tridosium Pentetate	117. Zoledronic Acid
118. Zonisamide <i>(Received)</i>		

Small Molecules (Drug Products)—As of April 22, 2008

1. Abacavir Sulfate, Lamivudine, and Zidovudine Tablets	2. Acarbose Tablets	3. Acetaminophen, Butalbital, Caffeine, and Codeine Phosphate Capsules
4. Acetaminophen, Clemastine Fumarate and Pseudoephedrine Hydrochloride Tablets	5. Acetazolamide Extended-Release Capsules	6. Albuterol and Ipratropium Bromide Inhalation Aerosol
7. Albuterol and Ipratropium Bromide Inhalation Solution	8. Albuterol Extended-Release Tablets	9. Albuterol Inhalation Aerosol
10. Albuterol Sulfate Inhalation Solution	11. Albuterol Sulfate Oral Solution	12. Alendronate Sodium Oral Solution
13. Alfuzosin Extended-Release Tablets	14. Allopurinol for Injection	15. Alprazolam Extended-Release Tablets
16. Alprostadil Urethral Suppository	17. Aminopropazine Fumarate and Neomycin Sulfate Tablets	18. Aminopropazine Fumarate Injection
19. Aminopropazine Fumarate Tablets	20. Aminopterin Sodium Tablets	21. Amiodarone Hydrochloride Injection
22. Amlodipine and Benazepril Hydrochloride Capsules	23. Amphotericin B Injection	24. Anagrelide Hydrochloride Capsules (Received)
25. Arsenic Trioxide Injection	26. Atovaquone and Proguanil Hydrochloride Tablets	27. Atovaquone Tablets
28. Auranofin Capsules	29. Azatadine Maleate and Pseudoephedrine Sulfate Extended-Release Tablets	30. Azelaic Acid Cream
31. Azithromycin for Injection (Received)	32. Azithromycin Tablets (Received)	33. Baclofen Injection
34. Balsalazide Disodium Capsules	35. Beclomethasone Dipropionate Inhalation Aerosol	36. Beclomethasone Dipropionate Nasal Suspension
37. Benazepril Hydrochloride and Hydrochlorothiazide Tablets	38. Bentoquatam Topical Suspension	39. Benzocaine and Cetylpyridinium Chloride Lozenges
40. Benzocaine and Menthol Lotion	41. Benzphetamine Hydrochloride Tablets	42. Bivalirudin Injection
43. Brompheniramine Maleate, Dextromethorphan Hydrobromide, and Pseudoephedrine Hydrochloride Oral Solution	44. Budesonide Inhalation Aerosol	45. Bupivacaine and Lidocaine Hydrochlorides Injection
46. Buprenorphine Hydrochloride Injection	47. Butalbital and Acetaminophen Capsules	48. Butalbital and Acetaminophen Tablets
49. Cabergoline Tablets (Received)	50. Calcipotriene Cream	51. Calcipotriene Ointment
52. Calcipotriene Topical Solution	53. Calcitriol Capsules	54. Calcitriol Oral Solution
55. Calcium Acetate Capsules	56. Calcium Trisodium Pentetate Injection	57. Calfactant Intratracheal Suspension
58. Carbidopa and Levodopa Extended-Release Tablets (Received)	59. Carbidopa and Levodopa Tablets For Oral Suspension (Received)	60. Carbidopa, Levodopa, and Entacapone Tablets
61. Carmustine For Injection (Received)	62. Carmustine Implant	63. Cefdinir Tablets
64. Cefditoren Pivoxil Tablets	65. Ceftibuten Capsules	66. Ceftibuten For Oral Suspension
67. Ceftiofur Hydrochloride Oral Suspension	68. Cetirizine Hydrochloride Tablets (Received)	69. Cetrorelix Injection
70. Cevimeline Hydrochloride Capsules	71. Chloroxine Cream	72. Chlorpromazine Hydrochloride Extended-Release Capsules
73. Choline and Magnesium Salicylates Oral Solution	74. Choline and Magnesium Salicylates Tablets	75. Choline Salicylate Oral Solution (Received)
76. Ciclopirox Shampoo	77. Ciclopirox Topical Gel	78. Ciclopirox Topical Solution (Received)
79. Cimetidine Oral Solution	80. Ciprofloxacin Extended-Release Tablets (Added)	81. Ciprofloxacin Hydrochloride and Hydrocortisone Otic Suspension
82. Ciprofloxacin Otic Solution	83. Cisplatin Injection (Added)	84. Citalopram Hydrobromide Oral Solution
85. Citric Acid, Gluconolactone, and Magnesium Carbonate Irrigation	86. Cladribine Injection	87. Clemastine Fumarate Syrup
88. Clobetasol Propionate Gel	89. Clorazepate Dipotassium Capsules	90. Clorazepate Dipotassium Extended-Release Tablets
91. Clotrimazole and Betamethasone Dipropionate Lotion	92. Compound Undecylenic Acid Cream	93. Compound Undecylenic Acid Topical Powder
94. Conjugated Estrogens and Medroxyprogesterone Acetate Tablets	95. Cyclosporine Modified Capsules	96. Cyclosporine Modified Oral Solution
97. Cyclosporine Ointment	98. Cyclosporine Topical Solution	99. Cysteamine Bitartrate Capsules
100. Cytarabine Liposome Injection	101. Dalfopristin and Quinupristin Injection	102. Dantrolene Sodium Oral Suspension
103. Dapiprazole for Ophthalmic Solution	104. Desirudin for Injection	105. Desonide Cream

Small Molecules (Drug Products)—As of April 22, 2008 (Continued)

106. Dexrazoxane for Injection	107. Dextroamphetamine Sulfate Extended-Release Capsules	108. Dextromethorphan Polistirex Extended-Release Oral Suspension
109. Diazepam Injectable Emulsion	110. Diclofenac Sodium Ophthalmic Solution	111. Diethylpropion Hydrochloride Extended-Release Tablets
112. Difenoxy Hydrochloride and Atropine Sulfate Tablets	113. Difloxacin Hydrochloride Tablets	114. Dihydroergotamine Mesylate Metered Spray
115. Diltiazem Hydrochloride Injection	116. Dinoprostone Vaginal Suppositories	117. Diphenhydramine Hydrochloride and Acetaminophen Tablets
118. Divalproex Sodium Delayed-Release Capsules	119. Dorzolamide and Timolol Ophthalmic Solution	120. Dorzolamide Ophthalmic Solution
121. Doxepin Hydrochloride Cream	122. Doxycycline Oral Gel	123. Econazole Nitrate Cream
124. Edrophonium Chloride and Atropine Sulfate Injection	125. Enalapril Maleate and Felodipine Extended-Release Tablets	126. Enalaprilat Injection (Received)
127. Entacapone Tablets	128. Ephedrine Sulfate and Guaifenesin Tablets	129. Epirubicin Hydrochloride for Injection (Added)
130. Epirubicin Hydrochloride Injection (Added)	131. Epoprostenol for Injection	132. Epoprostenol Injection
133. Escitalopram Oxalate Tablets (Received)	134. Esmolol Hydrochloride Injection	135. Esomeprazole Magnesium Capsules
136. Estazolam Tablets	137. Estramustine Phosphate Sodium Capsules	138. Ethanolamine Oleate Injection
139. Etidronate Disodium Injection Concentrate	140. Etomidate Injection	141. Exemestane Tablets
142. Famotidine Orally Disintegrating Tablets	143. Felbamate Oral Suspension	144. Felbamate Tablets
145. Fentanyl Lozenges	146. Famciclovir Tablets	147. Fentanyl Transdermal System (Received)
148. Ferrous Fumarate and Docusate Sodium Extended-Release Capsules	149. Fluconazole Oral Suspension	150. Fluconazole Tablets (Received)
151. Flunisolide Inhalation Aerosol	152. Flunisolide Nasal Spray	153. Fluocinolone Acetonide Shampoo
154. Fluorescein Sodium Ophthalmic Solution	155. Fluorometholone Ointment	156. Fluticasone Propionate Cream (Received)
157. Fluticasone Propionate Inhalation Powder	158. Fluticasone Propionate Ointment (Received)	159. Fluticasone Propionate Pressurized Inhaler
160. Foscarnet Sodium Injection	161. Fosfomycin for Oral Solution	162. Gabapentin Oral Solution
163. Gadobenate Dimeglumine Injection	164. Gallium Nitrate Injection	165. Ganciclovir Capsules
166. Ganirelix Acetate Injection	167. Gatifloxacin Injection	168. Gatifloxacin Tablets
169. Gentamicin Sulfate Oral Solution	170. Gentamicin Sulfate Soluble Powder	171. Glipizide Extended-Release Tablets
172. Granisetron Injection (Received)	173. Granisetron Tablets (Received)	174. Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets
175. Guaifenesin and Salts of Dextromethorphan and Pseudoephedrine Oral Solution	176. Guanidine Hydrochloride Tablets	177. Halobetasol Propionate Cream
178. Halobetasol Propionate Ointment	179. Haloperidol Decanoate Injection	180. Haloperidol Lactate Injection
181. Haloperidol Lactate Oral Concentrate	182. Hydralazine Hydrochloride and Hydrochlorothiazide Capsules	183. Hydrochlorothiazide Capsules
184. Hydrochlorothiazide Oral Solution	185. Hydrocodone Bitartrate and Acetaminophen Capsules	186. Hydrocodone Bitartrate and Acetaminophen Oral Solution
187. Hydrocodone Bitartrate and Aspirin Tablets	188. Hydrocodone Bitartrate and Guaifenesin Oral Solution	189. Hydrocodone Bitartrate and Homatropine Methylbromide Syrup
190. Hydrocortisone Acetate Dental Paste	191. Hydrocortisone Acetate Rectal Foam Aerosol	192. Hydrocortisone Butyrate Lotion
193. Hydroflumethiazide and Reserpine Tablets	194. Hydromorphone Hydrochloride Oral Solution (Received)	195. Hydroquinone Lotion
196. Ibandronate Sodium Tablets	197. Ibuprofen Capsules	198. Idarubicin Hydrochloride Injection
199. Imipramine Pamoate Capsules	200. Imiquimod Topical Cream	201. Ipratropium Bromide Inhalation Aerosol
202. Ipratropium Bromide Inhalation Solution	203. Irinotecan Hydrochloride Injection	204. Isosulfan Blue Injection
205. Isradipine Extended-Release Tablets	206. Itraconazole Injection	207. Itraconazole Oral Solution
208. Ketoconazole Cream	209. Ketoconazole Shampoo	210. Ketoprofen Capsules (Received)
211. Ketoprofen Extended-Release Capsules	212. Ketoprofen Tablets	213. Ketotifen Fumarate Ophthalmic Solution

Small Molecules (Drug Products)—As of April 22, 2008 (Continued)

214. Lactic Acid Lotion	215. Lamotrigine Tablets	216. Latanoprost Ophthalmic Solution
217. Leucovorin Calcium for Injection	218. Levetiracetam Tablets	219. Levocabastine Ophthalmic Suspension
220. Levofloxacin Solution	221. Lincomycin Hydrochloride and Spectinomycin Sulfate Soluble Powder	222. Liothyronine Injection
223. Lomustine Capsules	224. Lopinavir and Ritonavir Solution	225. Lopinavir Capsules
226. Lopinavir Solution	227. Loratadine Orally Disintegrating Tablets (Received)	228. Losartan Potassium Tablets (Received)
229. Mefloquine Hydrochloride Tablets	230. Melphalan for Injection	231. Mesalamine Suppositories
232. Mesoridazine Besylate Concentrate	233. Metaraminol Bitartrate Injection	234. Methacholine Chloride for Inhalation Solution
235. Methadone Hydrochloride Oral Concentrate	236. Methocarbamol and Aspirin Tablets	237. Methoxsalen Softgels
238. Methyclothiazide and Deserpidine Tablets	239. Methylphenidate Hydrochloride Chewable Tablets	240. Metipranolol Ophthalmic Solution
241. Metronidazole Capsules (Received)	242. Metronidazole Cream	243. Metronidazole Extended-Release Tablets
244. Metronidazole Hydrochloride for Injection	245. Metronidazole Lotion	246. Miconazole Nitrate Topical Aerosol
247. Midazolam Injection (Received)	248. Mifepristone Tablets	249. Miglitol Tablets
250. Milrinone Injection	251. Misoprostol Tablets (Received)	252. Moexipril Hydrochloride and Hydrochlorothiazide Tablets
253. Moexipril Hydrochloride Tablets	254. Molindone Hydrochloride Oral Solution	255. Morphine Sulfate for Injection Concentrate
256. Morphine Sulfate Oral Solution	257. Morphine Sulfate Oral Solution Concentrate	258. Morphine Sulfate Tablets
259. Mycophenolate Mofetil Capsules	260. Mycophenolate Mofetil Oral Solution	261. Mycophenolate Mofetil Tablets
262. Nalbuphine Hydrochloride Injection	263. Nalmefene Hydrochloride Injection	264. Naphazoline Hydrochloride and Pheniramine Maleate Ophthalmic Solution
265. Naphazoline Hydrochloride and Pheniramine Maleate Ophthalmic Solution	266. Naproxen Sodium Extended-Release Tablets	267. Nateglinide Tablets (Received)
268. Nedocromil Sodium Inhalation Aerosol	269. Neomycin Sulfate Oral Powder	270. Nicardipine Hydrochloride Capsules
271. Nilutamide Tablets	272. Nimodipine Capsules	273. Nisoldipine Extended-Release Tablets
274. Nitroglycerin Solution in Acrylic Adhesive	275. Nitroglycerin Transdermal System	276. Nizatidine Tablets
277. Ofloxacin in Dextrose Injection	278. Ofloxacin Injection	279. Olsalazine Sodium Capsules
280. Ondansetron Tablets (Received)	281. Orphenadrine Citrate Extended-Release Tablets (Received)	282. Orphenadrine Citrate, Aspirin, and Caffeine Tablets
283. Oxcarbazepine Suspension	284. Oxcarbazepine Tablets (Received)	285. Oxiconazole Cream
286. Pamidronate Disodium Injection	287. Pantoprazole Sodium for Injection	288. Pantoprazole Sodium Tablets
289. Paroxetine Hydrochloride Extended-Release Tablets	290. Paroxetine Oral Suspension	291. Pemirolast Potassium Ophthalmic Solution
292. Penicillin G Potassium Tablets for Oral Solution	293. Pentamidine Isethionate for Inhalation	294. Pentamidine Isethionate Injection (Received)
295. Pentazocine Hydrochloride and Acetaminophen Tablets	296. Phendimetrazine Tartrate Extended-Release Capsules	297. Phenobarbital Capsules
298. Phentermine Resin Complex Capsules	299. Phenylephrine Hydrochloride and Chlorpheniramine Maleate Extended-Release Capsules	300. Phenylephrine Hydrochloride, Chlorpheniramine Maleate, and Acetaminophen Extended-Release Tablets
301. Pilocarpine Hydrochloride Ophthalmic Gel	302. Pilocarpine Hydrochloride Ophthalmic Ointment	303. Pioglitazone Hydrochloride Tablets
304. Piperonyl Butoxide and Pyrethrins Aerosol Foam	305. Pirbuterol Acetate Inhalation Aerosol	306. Poractant Alpha Suspension
307. Porfimer Sodium for Injection	308. Povacrylate Solution	309. Povacrylate-Iodine Topical Solution
310. Povidone-Iodine Gauze	311. Povidone-Iodine Swabsticks	312. Povidone-Iodine Topical Aerosol Foam
313. Povidone-Iodine Vaginal Suppositories	314. Pramipexole Dihydrochloride Tablets	315. Prednisolone Sodium Phosphate Oral Solution

Small Molecules (Drug Products)—As of April 22, 2008 (Continued)

316. Prochlorperazine Maleate Extended-Release Capsules	317. Progesterone Capsules	318. Promethazine and Phenylephrine Hydrochlorides and Codeine Phosphate Syrup (Received)
319. Promethazine and Phenylephrine Hydrochlorides Syrup (Received)	320. Promethazine Hydrochloride and Codeine Phosphate Oral Solution (Received)	321. Promethazine Hydrochloride and Dextromethorphan Hydrobromide Syrup (Received)
322. Propafenone Hydrochloride Tablets	323. Pseudoephedrine Hydrochloride and Brompheniramine Maleate Extended-Release Tablets	324. Pseudoephedrine Hydrochloride and Naproxen Sodium Extended-Release Tablets
325. Pseudoephedrine Hydrochloride, Chlorpheniramine Maleate, and Codeine Phosphate Oral Solution	326. Pseudoephedrine Hydrochloride, Guaifenesin, and Codeine Phosphate Oral Solution	327. Pseudoephedrine Sulfate and Dexbrompheniramine Maleate Extended-Release Tablets
328. Pseudoephedrine Sulfate and Dexbrompheniramine Maleate Oral Solution	329. Pseudoephedrine Sulfate, Dexbrompheniramine Maleate, and Acetaminophen Extended-Release Tablets	330. Pyrilamine Maleate Injection
331. Quinapril Hydrochloride and Hydrochlorothiazide Tablets	332. Quinidine Sulfate Injection	333. Ramipril Capsules
334. Ranitidine Capsules	335. Rauwolfia Serpentina and Endroflumethiazide Tablets	336. Reserpine and Polythiazide Tablets
337. Rimantadine Hydrochloride Oral Solution	338. Risperidone Oral Solution (Received)	339. Risperidone Orally Disintegrating Tablets
340. Rivastigmine Tartrate Capsules (Received)	341. Rivastigmine Tartrate Oral Solution (Received)	342. Rocuronium Bromide Injection
343. Ropinirole Hydrochloride Tablets	344. Rosiglitazone Maleate Tablets	345. Salicylic Acid and Sulfur Cleansing Lotion
346. Salicylic Acid and Sulfur Lotion	347. Salicylic Acid and Sulfur Shampoo	348. Salicylic Acid Cream
349. Salicylic Acid Ointment	350. Salmeterol Inhalation Aerosol	351. Salmeterol Xinafoate Inhalation Powder
352. Scopolamine Transdermal System	353. Selegiline Hydrochloride Capsules	354. Sertraline Hydrochloride Oral Solution
355. Sibutramine Hydrochloride Capsules	356. Sodium Bicarbonate and Sodium Citrate for Oral Solution	357. Sodium Bicarbonate, Sodium Citrate, and Sodium Tartrate for Oral Suspension
358. Sodium Iodide Injection	359. Sodium Phenylbutyrate Oral Powder	360. Sodium Phenylbutyrate Tablets
361. Sodium Phosphates for Oral Suspension	362. Sodium Phosphates Tablets	363. Sodium Salicylate and Sulfur Shampoo
364. Sterile Talc Aerosol	365. Streptozocin for Injection	366. Sucralfate Oral Suspension
367. Sulconazole Nitrate Cream	368. Sulfacetamide Sodium and Fluorometholone Ophthalmic Suspension	369. Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution
370. Sulfasalazine Oral Suspension	371. Sulisobenzene Lotion	372. Sumatriptan Injection
373. Sumatriptan Tablets (Received)	374. Tacrolimus Capsules (Received)	375. Tacrolimus Injection
376. Tacrolimus Ointment	377. Tamsulosin Hydrochloride Capsules (Received)	378. Technetium Tc 99m Teboroxime Injection
379. Tenofovir Disoproxil Fumarate Tablets (Received)	380. Terazosin Capsules (Received)	381. Terazosin Tablets (Received)
382. Terbinafine Hydrochloride Cream	383. Terbinafine Tablets (Received)	384. Terbinafine Topical Solution
385. Terconazole Vaginal Cream	386. Terconazole Vaginal Suppositories	387. Testosterone Transdermal Gel
388. Testosterone Transdermal System	389. Tetracycline Hydrochloride Periodontal Fiber	390. Theophylline Extended-Release Tablets
391. Tioconazole Vaginal Ointment	392. Tiopronin Tablets	393. Tolnaftate Topical Aerosol Solution
394. Topiramate Capsules (Received)	395. Topiramate Tablets (Received)	396. Toremide Injection
397. Toremide Tablets (Received)	398. Trandolapril and Verapamil Hydrochloride Extended-Release Tablets	399. Trandolapril Tablets
400. Tranexamic Acid Injection	401. Tranylcypromine Sulfate Tablets (Received)	402. Tretinoin Capsules
403. Tretinoin Microsphere Gel	404. Triamcinolone Acetonide Nasal Suspension	405. Trifluridine Ophthalmic Solution
406. Trimetrexate for Injection	407. Trimipramine Maleate Capsules	408. Triprolidine and Pseudoephedrine Hydrochlorides and Codeine Phosphate Syrup
409. Trolamine Salicylate Cream	410. Trolamine Salicylate Gel	411. Trolamine Salicylate Topical Emulsion
412. Undecylenic Acid Topical Foam Aerosol	413. Urea Cream	414. Vecuronium Bromide for Injection

Small Molecules (Drug Products)—As of April 22, 2008 (Continued)

415. Venlafaxine Extended-Release Capsules <i>(Received)</i>	416. Venlafaxine Tablets <i>(Received)</i>	417. Verapamil Hydrochloride Capsules
418. Verapamil Hydrochloride Extended-Release Capsules	419. Voriconazole Injection	420. Voriconazole Oral Suspension
421. Voriconazole Tablets	422. Yttrium Y-90 Chloride Solution	423. Yttrium Y-90 Glass Microspheres
424. Yttrium Y-90 Microspheres Injection	425. Zaleplon Capsules	426. Zidovudine and Lamivudine Tablets <i>(Received)</i>
427. Zinc Acetate Capsules	428. Zinc Tridosium Pentetate Injection	429. Ziprasidone Hydrochloride Capsules
430. Zoledronic Acid for Injection	431. Zonisamide Capsules <i>(Received)</i>	

Excipients—As of April 22, 2008

1. Acetone Sodium Bisulfite	2. Acetylated Monoglycerides	3. Aconitic Acid (Achilleic Acid)
4. Acrylic Acid–Octyl Acrylate Copolymer	5. Albumin Colloidal	6. Aliphatic Polyesters
7. Allantoin–Sodium Pyrrolidone Carboxylate	8. Aluminum Ammonium Sulfate	9. Aluminum Lactate
10. Aluminum Oxide	11. Aluminum Potassium Sulfate	12. Aluminum Silicate
13. Aluminum Sodium Sulfate	14. Aluminum Stearate	15. Ammonium Bicarbonate
16. Ammonium Calcium Alginate	17. Ammonium Phosphate	18. Batylalcohol Monostearate
19. Beeswax, Synthetic	20. Benzododecinium Bromide	21. Benzyl Chloride
22. Benzyl Nicotinate	23. Beta Naphthol	24. Brominated Vegetable Oil
25. Butadiene–Styrene Rubber	26. Butylated Hydromethylphenol	27. Butylene Glycol
28. Butylphthalyl Butylglycolate	29. Calcium Acid Pyrophosphate	30. Calcium Alginate
31. Calcium Alginate and Ammonium Alginate	32. Calcium Bromide	33. Calcium Chloride Solution
34. Calcium Phosphate Monobasic	35. Calcium Propionate	36. Calcium Pyrophosphate
37. Calcium Sorbate	38. Calcium Stearoyl Lactylate	39. Caldiamide Sodium
40. Calteridol Calcium	41. Capric Acid	42. Caprylic/Capric Diglycerol Succinate
43. Carbon	44. Carboxymethyl Starch	45. Carboxymethylamylopectin Sodium
46. Carboxymethylcellulose Potassium	47. Cetostearyl Isononanoate	48. Chlorodifluoroethane
49. Cholic Acid	50. Cinnamaldehyde	51. Cocamide Diethanolamine
52. Cocamide Oxide	53. Cocoyl Caprylocaprate	54. Crystal Gum
55. Cutina	56. Cystine	57. Dammar Gum
58. Decanoic Acid	59. Decyl Oleate	60. Desoxycholic Acid
61. Dextrin Palmitate	62. Dextrins Modified	63. Diacetyl Tartaric Acid Esters of Mono- and Diglycerides
64. Dicyetyl Phosphate	65. Dichlorofluoromethane	66. Diethyl Sebacate
67. Difluoroethane	68. Diglycol Stearate	69. Diisobutyl Adipate
70. Diisopropyl Adipate	71. Diisopropylbenzothiazyl-2-Sulfenamide	72. Dilauryl Thiodipropionate
73. Dimethyl Dicarboxylate	74. Dimyristoyl Lecithin	75. Dimyristoyl Phosphatidylglycerol
76. Dipropylene Glycol	77. Disodium Edisylate	78. Disodium Guanylate
79. Disodium Inosinate	80. Disodium Monooleamide Sulfasuccinate	81. D-Mannose
82. Docusate Sodium/Sodium Benzoate	83. Erythrosine	84. Ethoxylated Mono- and Diglycerides
85. Ethoxyquin	86. Ethyl Hexanediol	87. Ethyl Linoleate
88. Ethyl Maltol <i>(Received)</i>	89. Ethylene Dichloride	90. Ethylurea
91. Ferric Ammonium Citrate	92. Ferric Citrate	93. Ferric Oxide, Brown
94. Ferric Phosphate	95. Ferric Pyrophosphate	96. Ferrous Citrate
97. Ferrous Glycinate	98. Ferrous Lactate	99. Fluorochlorohydrocarbons
100. Formic Acid	101. Furcelleran	102. Gentistic Acid
103. Geraniol	104. Glutamic Acid Hydrochloride	105. Gluten
106. Glycerol Ester of Gum Rosin (Ester Gum)	107. Glyceryl Laurate	108. Glyceryl Palmitate
109. Glyceryl Ricinoleate	110. Glyceryl Tristearate	111. Glycine Hydrochloride
112. Glycofurofural	113. Glycol Stearate	114. Heptafluoropropane
115. Heptylparaben	116. Hexadecyl Isostearate	117. Hexane
118. Hexanetriol(-1,2,6-)	119. Hydrocarbon Gel	120. Hydroxyethylmethylcellulose
121. Hydroxylated Lecithin	122. Indigotine	123. Iron Carbonyl

Excipients—As of April 22, 2008 (Continued)

124. Iron Subcarbonate	125. Isobutylated-Isoprene Copolymer	126. Isooctylacrylate
127. Isopropyl Isostearate	128. Isopropyl Stearate	129. Isostearic Acid
130. Isostearyl Alcohol	131. Lactobionic Acid	132. Lactose Ferrin, Bovine
133. Lactylated Fatty Acid Esters of Glycerol and Propylene Glycol	134. Lactylic Esters of Fatty Acids	135. Lanolin (Wool Fat), Hydrogenated
136. Lanolin Alcohols, Acetylated	137. Lanolin Hydrous	138. L-Ascorbyl Stearate
139. Lauramine Oxide	140. Lauric Myristic Diethanolamide	141. Lauric Acid
142. Lauric Diethanolamide	143. Lavender Oil	144. L-Cysteine Monohydrochloride
145. Lecithin, Hydroxylated	146. L-Glutamic Acid <i>(Received)</i>	147. Linoleic Acid <i>(Received)</i>
148. L-Leucine	149. Macrogol Sorbitan Tristearate	150. Macrogolglycerol Cocoates
151. Macrogolglycerol Triisostearate	152. Magnesium Aluminum Silicate Hydrate	153. Magnesium Aspartame Dihydrate
154. Magnesium Aspartate	155. Magnesium Phosphate Tribasic	156. Magnesium Phosphate, Diabasic, Trihydrate
157. Magnesium Tartrate	158. Malt Syrup	159. Maltitol Syrup
160. Maltol Isobutyrate	161. Manganese Chloride	162. Manganese Citrate
163. Manganese Glycerophosphate	164. Manganese Hypophosphite	165. Medical Antifoam Emulsion C
166. Medronate Disodium	167. Medronic Acid	168. Methyl Chloride
169. Methylchloroisothiazolinone	170. Methylisothiazolinone	171. Microcrystalline Cellulose, Silicified <i>(Received)</i>
172. Mineral Spirits	173. Monoisostearyl Glyceryl Ester	174. Monopotassium Glutamate Monohydrate
175. Monosodium Citrate	176. Mullein Leaf	177. Myristyl Gamma-Picolinium Chloride
178. Myristyl Lactate	179. <i>N,N</i> -Bis(2-Hydroxyethyl)Stearamide	180. <i>N</i> -Acetyl-L-Methionine
181. Naphtha	182. <i>N</i> -Methylpyrrolidone <i>(Received)</i>	183. Non-Pareil Seeds
184. Nutmeg Oil	185. Octanoic Acid	186. Oxystearin
187. Palm Kernel Oil <i>(Received)</i>	188. Pentasodium Triphosphate	189. Pentetate Calcium Trisodium
190. Pentetate Pentasodium	191. Phenprobamate	192. Phenylmercuric Acetate
193. Phenylmercuric Nitrate	194. Pine Oil	195. Polacrilin
196. Polyglycerol Esters of Fatty Acids	197. Polyglycerol Polyricinoleic Acid	198. Polyoxyethylene Castor Oil (USP has 35)
199. Polyoxyl Stearate (USP has 40)	200. Polypropylene Oleate	201. Polypropylene Stearyl Ether
202. Polysorbate 65	203. Polyvinylacetal Diethylanoacetate	204. Polyvinylpyrrolidone
205. Polyvinylpyrrolidone Ethylcellulose	206. Potassium Acid Tartrate	207. Potassium Bromate
208. Potassium Carbonate Solution	209. Potassium Dichloroisocyanurate	210. Potassium Gibberellate
211. Potassium Glycerophosphate	212. Potassium Iodate	213. Potassium Nitrite
214. Potassium Phosphate	215. Potassium Phosphate Tribasic	216. Potassium Polymetaphosphate
217. Potassium Pyrophosphate	218. Potassium Stearate	219. Potassium Sulfate
220. Potassium Sulfite	221. Potassium Tripolyphosphate	222. Propyl Propionate
223. Propylene Glycol Diacetate	224. Propylene Glycol Mono- and Diesters	225. Rice Bran Wax
226. Rosin	227. Silicone	228. Sodium Acid Pyrophosphate
229. Sodium Aluminosilicate <i>(Received)</i>	230. Sodium Aluminum Phosphate Acidic	231. Sodium Aluminum Phosphate Basic
232. Sodium Aspartate	233. Sodium Bisulfate	234. Sodium Bisulfite
235. Sodium Carbonate Hydrate	236. Sodium Carboxymethyl Betaglucan	237. Sodium Caseinate
238. Sodium Chlorate	239. Sodium Citrate, Dibasic	240. Sodium Citrate, Monobasic
241. Sodium Dehydroacetate	242. Sodium Diacetate	243. Sodium Erythorbate
244. Sodium Ferric Pyrophosphate	245. Sodium Ferrocyanide	246. Sodium Hypophosphite <i>(Received)</i>
247. Sodium Laureth Sulfate	248. Sodium Lauroyl Sarcosinate	249. Sodium Lauryl Sulfoacetate
250. Sodium Magnesium Aluminosilicate	251. Sodium Magnesium Silicate	252. Sodium Malate
253. Sodium Metaphosphate, Insoluble	254. Sodium Metasilicate	255. Sodium Methylate
256. Sodium Polyphosphates Glassy	257. Sodium Potassium Tripolyphosphate	258. Sodium Pyrophosphate
259. Sodium Pyrrolidone Carboxylate	260. Sodium Sesquicarbonate	261. Sodium Sesquinoate
262. Sodium Stearoyl Lactylate	263. Sodium Thiomalate	264. Sodium Trimetaphosphate
265. Sodium Trioleate	266. Sodium Tripolyphosphate	267. Soy Polysaccharides
268. Stannous Tartrate	269. Starch, Pregelatinized Corn	270. Starch, Pregelatinized Tapioca

Excipients—As of April 22, 2008 (Continued)

271. Stearalkonium Chloride	272. Stearyl Citrate	273. Stearyl Monoglyceridyl Citrate
274. Succinylated Monoglycerides	275. Sucrose Acetate Isobutyrate	276. Sucrose Fatty Acid Esters
277. Sucrose Stearate	278. Sugar Fruit Fine	279. Sulfobutyl Ether Beta Cyclodextran
280. Tallow	281. Tallow Glycerides	282. Tallow Oil
283. Tetrafluoroethane	284. Thioglycerol	285. Thyme Oil
286. Tribehenin	287. Tricetareth-4 Phosphate	288. Trichloroethylene
289. Trimyristin	290. Trisodium Citrate	291. Trolamine Lauryl Sulfate
292. Vegetable Oil	293. Wheat Flour	294. Wheat Germ Oil
295. Wheat Gluten (Received)	296. Whey	

INSTRUCTIONS TO AUTHORS

Contributions in the form of original research reports, evaluations of new and existing compendial methods, and other commentaries and articles relevant to drug standards or to *USP–NF* revision will be considered for publication in *Pharmacopeial Forum* under the section *Stimuli to the Revision Process*. Manuscripts are received with the explicit understanding that they have not been published previously in any language or medium and that they are not simultaneously under consideration by any other publication.

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Abstract—Include an abstract of not more than 250 words stating the purpose and the results or conclusions of the article.

Style and Usage—*Stimuli* articles generally follow the current *Chicago Manual of Style* except in scientific usage (numbers, abbreviations, etc.). For the latter, authors should use the current *AMA Manual of Style* or the current *ACS Style Guide*. Authors may usefully consult a current copy of *Pharmacopeial Forum*.

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Pharmacopeial Forum
Executive Secretariat, USP
12601 Twinbrook Pkwy.
Rockville, MD 20852

The Inhalation Ad Hoc Advisory Panel for the *USP* Performance Tests of Inhalation Dosage Forms

Vivian A. Gray (Co-Chair), Anthony J. Hickey, PhD, DSc (Co-Chair), Patrick Balmer, PhD, Neal M. Davies, PhD, RPh, Craig Dunbar, PhD, Thomas S. Foster, PharmD (Chair, Biopharmaceutics Expert Committee), Bo L. Olsson, PhD, Masahiro Sakagami, PhD, Vinod P. Shah, PhD (Scientific Liaison), Michael J. Smurthwaite, BSc, John M. Veranth, PhD, and Kakhkashan Zaidi, PhD
The Inhalation Ad Hoc Advisory Panel for the USP Performance Tests of Inhalation Dosage Forms

ABSTRACT The *US Pharmacopeia (USP)* contains standards for tests, procedures, and acceptance criteria for inhalation dosage forms that are administered orally and intranasally. Product quality and performance tests are concerned primarily with the assessment of drug delivery and deposition in the respiratory tract. This *Stimuli* article evaluates the scientific rationale, if any, for in vitro dissolution tests for inhalation dosage forms. Studies that determine the profiles and kinetics of dissolution for inhaled therapeutics have been performed, but a literature review could not find compelling evidence suggesting that such dissolution testing is kinetically and/or clinically crucial for currently approved inhalation drug products. Even so, because of the possible development of novel inhalation products with modified or controlled dissolution and release, a *USP* standard for assessing dissolution of inhalation dosage forms may be considered in the future if scientifically warranted.

Use of Scanning Electron Microscopy in the Authentication of Botanicals

Vaishali C. Joshi,¹ Ikhlas A. Khan,^{2*} and Maged H.M. Sharaf^{†‡}

ABSTRACT This article provides an overview of scanning electron microscopy and its applications in the identification and authentication of botanicals. The USP Dietary Supplements—Botanicals Expert Committee plans to include scanning electron microscopy as an additional tool in addition to those currently included in *USP* General Chapter *Identification of Articles of Botanical Origin* (563) (1). The objectives of this *Stimuli* article are to initiate discussion, to solicit public comments, and to invite the participation of interested parties in the efforts of the Expert Committee.

USP Dictionary of USAN and International Drug Names 2008 USP DICTIONARY SUPPLEMENT 2

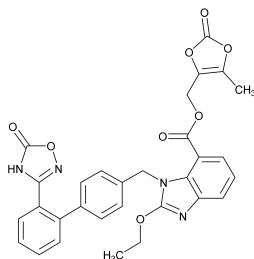
IMPORTANT—Save this Supplement. This and all supplements appearing in *PF* are needed to keep the 2008 edition of the USP Dictionary (USPD) up-to-date. The cumulative contents of the supplements to the current (2008) edition will be included in the next complete edition of the Dictionary.

Newly Approved United States Adopted Names (USAN), Released for Publication

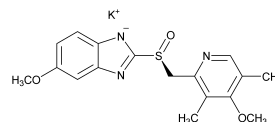
The following are newly established United States Adopted Names (USAN). These names will not be listed cumulatively; see preceding and succeeding numbers of *PF* for other new USAN to supplement the Dictionary main volume.

Azilsartan Medoxomil [2007] (ay' zil sar' tan me dox' oh mil).

$C_{30}H_{24}N_4O_8$. 568.50. (1) 1*H*-Benzimidazole-7-carboxylic acid, 1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)[1,1'-biphenyl]-4-yl]methyl]-2-ethoxy-, (5-methyl-2-oxo-1,3-dioxol-4-yl)-methyl ester; (2) (5-Methyl-2-oxo-1,3-dioxol-4-yl)methyl 2-ethoxy-1-(2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)biphenyl-4-yl)methyl-1*H*-benzo[d]imidazole-7-carboxylate. *CAS*-863031-21-4. INN. *Treatment of hypertension.* ◊*TAK-491*



Esomeprazole Potassium [2007] (es' oh mep' ra zole poe tas' ee um). $C_{17}H_{18}KN_3O_3S$. 383.50. (1) 1*H*-Benzimidazole, 6-methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-, potassium salt (1:1); (2) (-)-5-Methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulfinyl]-1*H*-benzimidazole potassium salt. *CAS*-161796-84-5. *Treatment of GERD patients with a history of erosive esophagitis.*



Revisions of United States Adopted Names (USAN)

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

Olanzapine Pamoate

Change molecular weight to read:

718.82

Poractant Alfa

Change definition to read:

An extract of porcine lung containing not less than 90% of phospholipids, about 1% of hydrophobic proteins (SP-B and SP-C), and about 9% of other lipids.

Safinamide

Change chemical name to read:

(+)-(*S*)-2-[[*p*-[(*m*-Fluorobenzyl)oxy]benzyl]amino]propionamide

Teriflunomide

Change chemical name to read:

(*Z*)-2-Cyano- α,α,α -trifluoro-3-hydroxy-*p*-crotonoluidide

Terbogrel

Change chemical name to read:

(1) (*E*)-6-[3-[[[(Cyanoamino)[(1,1-dimethylethyl)amino]methylene]amino]phenyl]-6-(3-pyridinyl)-5-hexenoic acid;

Terdecamycin

Change chemical name to read:

4-Methyl-1-piperazinecarboxylic acid, 7-ester with (-)-*N*-[(1*S*,2*R*,3*E*,5*E*,7*S*,9*E*,11*E*,13*S*,15*R*,19*R*)-7,13-dihydroxy-1,4,10,19-tetramethyl-17,18-dioxo-16-oxabicyclo[13.2.2]nonadeca-3,5,9,11-tetraen-2-yl]pyruvamide

Tiletamine Hydrochloride

Change chemical name to read:

(1) Cyclohexanone, 2-(ethylamino)-2-(2-thienyl)-, hydrochloride;

Proposed and Recommended International Nonproprietary Names

International Nonproprietary Names (INN) are devised by the World Health Organization (WHO).

Under its charter, the WHO is empowered simply to *recommend* specific actions or procedures to its Member States. This limitation is incorporated into the WHO program concerned with the selection of international nonproprietary names for pharmaceutical substances, in that the WHO first publishes the selected names as *proposals* (“Proposed International Nonproprietary Names”). A period of four months from the date of publication in *WHO Drug Information* is allowed for entering comments on, or objections to, any proposal on the part of

Member States or other interested parties. In general, an objection reflects a belief that the proposal concerned is confusingly close to (i.e., conflicts with) a name already in use, perhaps in only a restricted area in which the party has a proprietary interest in the form of trademark rights. In the event that no objection is received, the WHO proceeds with listing and publishing the names so devised as *recommendations* (“Recommended International Nonproprietary Names”), which many Member States then recognize as the sole or preferred nonproprietary name for use within their respective territories.

Proposed International Nonproprietary Names—List 98

The following 62 names have been selected by the World Health Organization (WHO) as Proposed International Nonproprietary Names.

This list, with chemical names or descriptions and the molecular formulae, appears in *WHO Drug Information*, Vol. 21, No. 4, 2007.

Suggested INN	Category
Adiplon	<i>Sedative, hypnotic</i>
Agatolimod	<i>Antineoplastic</i>
Alacizumab Pegol	<i>Antineoplastic</i>
Aleplasinin	<i>Inhibitor of plasminogen activator inhibitor-type1</i>
Almorexant	<i>Orexin-receptor antagonist</i>
Amolimogene Bepiplasmid	<i>Immunomodulator, immunostimulant</i>
Amsilarotene	<i>Antineoplastic</i>
Anacetrapib	<i>Antihyperlipidaemic</i>
Anrukinzumab	<i>Immunomodulator</i>
Baminercept	<i>Immunomodulator</i>
Bentamapimod	<i>Immunomodulator</i>
Berubicin	<i>Antineoplastic antibiotic</i>
Besifloxacin	<i>Antibacterial</i>
Betrixaban	<i>Blood coagulation factor Xa inhibitor</i>
Briobacept	<i>Immunomodulator</i>
Cabazitaxel	<i>Antineoplastic</i>
Cariprazine	<i>Antipsychotic</i>
Carmegliptin	<i>Hypoglycaemic</i>
Cobiprostone	<i>Prostaglandin derivative</i>
Conestat Alfa	<i>Enzyme inhibitor</i>
Dacetuzumab	<i>Immunomodulator, antineoplastic</i>
Daporinad	<i>Antineoplastic</i>
Darinaparsin	<i>Antineoplastic</i>
Deforolimus	<i>Antineoplastic</i>
Dexnebulolol	<i>β-adrenoreceptor antagonist</i>
Emricasan	<i>Caspase inhibitor</i>
Eribaxaban	<i>Blood coagulation factor Xa inhibitor</i>
Ezatiostat	<i>Glutathione-S-transferase inhibitor</i>
Fasobegron	<i>B3-adrenoreceptor agonists</i>
Favipiravir	<i>Antiviral</i>

Suggested INN	Category
Fermagate	<i>Phosphate binder</i>
Flopristin	<i>Antibacterial</i>
Folitixorin	<i>Folate derivative</i>
Ibodutant	<i>Tachykinin receptor antagonist</i>
Imeglimin	<i>Hypoglycaemic</i>
Laromustine	<i>Antineoplastic</i>
Levonebivolol	<i>β-adrenoreceptor antagonist</i>
Linopristin	<i>Antibacterial</i>
Lucatumumab	<i>Antineoplastic</i>
Milatuzumab	<i>Antineoplastic</i>
Mirabegron	<i>B3-adrenoreceptor agonists</i>
Monepantel	<i>Anthelmintic (veterinary use)</i>
Nelivaptan	<i>Vasopressin receptor antagonist</i>
Nesbuvir	<i>Antiviral</i>
Odanacatib	<i>Cathepsin inhibitor</i>
Omacetaxine Mepesuccinate	<i>Antineoplastic</i>
Otelixizumab	<i>Immunomodulator</i>
Pegloticase	<i>Enzyme</i>
Preladenant	<i>Adenosine receptor antagonist</i>
Quarfloxin	<i>Antineoplastic</i>
Radiprodil	<i>NMDA receptors antagonist</i>
Remogliflozin Etabonate	<i>Hypoglycaemic</i>
Retosiban	<i>Oxytocin antagonist</i>
Riociguat	<i>Guanylate cyclase activator/stimulator</i>
Rolofylline	<i>Nootropic agent</i>
Tenatumomab	<i>Antineoplastic</i>
Tertomotide	<i>Immunological agent for active immunization</i>
Tigatuzumab	<i>Antineoplastic</i>
Tiprolisant	<i>Histamine-H3 receptor inverse agonist</i>
Velaglucerase Alfa	<i>Enzyme</i>
Veltuzumab	<i>Antineoplastic</i>
Viquidacin	<i>Antibacterial</i>

Recommended International Nonproprietary Names—List 59

The following 77 names have been selected by the World Health Organization (WHO) as Recommended International Nonproprietary

Names. This list, with chemical names or descriptions and the molecular formulae, appears in *WHO Drug Information*, Vol. 22, No. 1, 2008.

Albiglutide
Albinterferon Alfa-2b
Anamorelin
Apremilast
Arbaclofen Placarbil
Arterolane
Azilsartan Medoxomil
Azoximer Bromide
Begacestat
Belatacept
Belinostat
Boceprevir
Brivanib Alaninate
Canakinumab
Carfilzomib
Ceftaroline Fosamil
Cenersen
Choline Fenofibrate
Cinaciguat
Contusugene Ladenovec
Dapagliflozin
Delimotecan
Dovitinib
Eldecalcitol
Elvitegravir
Epetirimod
Epoetin Kappa
Eribulin
Faxeladol
Ferric Carboxymaltose
Flvagafran
Gantenerumab
Golotimod
Ibalizumab
Idrabiotaparinux Sodium
Laropiprant
Levamlodipine
Lonaprisan
Metenkefalin

Milveterol
Motesanib
Nepidermin
Neratinib
Perampanel
Peretinoin
Pexacerfont
Pimavanserin
Piragliatin
Pomalidomide
Posaraprost
Pyronaridine
Rabeximod
Raltegravir
Regrelor
Rolapitant
Romiplostim
Ronacaleret
Ropidoxuridine
Rosonabant
Salirasib
Sergliflozin Etabonate
Sitimagene Ceradenovec
Sotrastaurin
Taranabant
Tarenflurbil
Teplizumab
Terameprocol
Thrombin Alfa
Totrombopag
Trabedersen
Trelanserin
Tremelimumab
Tridecactide
Tropantol
Vatreptacog Alfa (activated)
Velimogene Aliplasmid
Voclosporin