

**April 2009****Email Notice**

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For all the latest information, visit www.usp.org

USP Catalogs

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In order to provide you more current information in each Notice we are changing the delivery date to better coincide with internal updating of relevant USP information. Starting in April, the Email Notice will be sent out the third Wednesday of the month. Look for the May Email Notice on May 20.

Reference Standards Highlights

Below are several tables with the latest Reference Standard information including out-of-stock items now available; new Reference Standards released in March 2009; backordered items with estimated availability dates; items that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.

Please contact your USP Customer Service Representative to place an order at +1 (301) 881-0666 or 1-800-227-8772. European customers can call 00-800-4875-5555. You can also order online at www.usp.org/products.

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New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1151924	Cyanidin Chloride	25 mg	F0I010	\$525
1231604	Ecamsule Triethanolamine	200 mg	F0H444	\$194
1269902	Fentanyl CII	100 mg	F0H364	\$299
1288339	Ganciclovir Mono-N-Methyl Valinate	10 mg	F0I023	\$605
1443602	Midazolam Hydrochloride CIV (AS)	200 mg	F0G152	\$275
1448027	Morphine Sulfate Related Compound B CII	20 mg	F0H435	\$605
1457607	Nateglinide	200 mg	F0I013	\$194
1457629	Nateglinide Related Compound B	10 mg	F0I032	\$605
1570326	Propafenone Related Compound B	50 mg	F0I039	\$605
1612517	Sertraline Hydrochloride Racemic Mixture	25 mg	F0I050	\$605
1612539	Sertraline Hydrochloride	100 mg	F0I030	\$495
1673001	Travoprost	3 mL	F0I036	\$194
1673012	Travoprost Related Compound A	1.5 mL	F0I012	\$605
1673839	Trenbolone Acetate System Suitability Mixture CIII	30 mg	F0I047	\$605
1708730	Valrubicin	100 mg	F0I003	\$595

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1137005	Clindamycin Palmitate Hydrochloride	500 mg	H0I037	\$532
1152009	Cyanocobalamin	1.5 g	O0H288	\$194
1270446	Fexofenadine Related Compound C (AS)	15 mg	G0I059	\$605
1291559	Ginkgo Terpene Lactones	50 mg	G0I051	\$399
1449530	Nabumetone Related Compound A	15 mg	G0I062	\$605
1499414	Paricalcitol Solution	3 mL	G1I063	\$310
1557000	Prednisolone Sodium Phosphate	500 mg	F1H347	\$194
1683504	Trientine Hydrochloride	200 mg	G0H377	\$194
1686309	Trifluridine	200 mg	G0I041	\$224

Backorder Availability Estimates, April 6, 2009

Catalog #	Description	Expected Availability*
1471007	Norethynodrel (200 mg)	Q2/09
1500262	Paroxetine Related Compound E Mixture (25 mg)	Q3/09

*Dates are targets and may change at any time. Q2/09=April–June 2009, Q3/09=July–September 2009

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Items with New Package Size or New Description

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1152009	Cyanocobalamin*	1.5 g	1.5 g	O0H288	\$194
1270446	Fexofenadine Related Compound C (AS)**	15 mg	15 mg	G0I059	\$605
1557000	Prednisolone Sodium Phosphate	100 mg	500 mg	F1H347	\$194
1683504	Trientine Hydrochloride	125 mg	200 mg	G0H377	\$194

*The description has changed from 10.7 mcg/mg to 10.4 mcg/mg

**The description of this RS has changed from (+)-4-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]-isopropylbenzene to (+/-)-4-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]-isopropylbenzene hydrochloride)

RS Lots That are No Longer Valid

These Tables lists previous RS lots that are (or will soon be) no longer valid for official use. If you still have any of these materials on hand, do not use them for compendial testing purposes after the last day of the month for the valid use dates listed. To test products, always be sure you use a current, valid lot of USP RS. Current lot numbers and valid use dates for previous lots are available in the USP Catalog online at www.usp.org: click on the USP Products link and look up the RS of interest.

No Longer Valid as of March 31, 2009					
Catalog #	Description	Previous Lot/ Valid Use Date		Current Lot	Price (USD)
1047503	Bacitracin (1 g) (AS) (Susceptibility disk standard)	G1C254	(03/09)	H0H096	\$194
1067704	Betamethasone Dipropionate (125 mg)	K0C229	(03/09)	L0G377	\$154
1123000	Chlorpheniramine Maleate (125 mg)	M0B020	(03/09)	N0G316	\$154
1046078	Desosaminylazithromycin (15 mg)	F0E067	(03/09)	G0H171	\$605
1185008	Diazepam CIV (100 mg)	I1C364	(03/09)	I2G270	\$257
1225000	Doxapram Hydrochloride (200 mg)	F4C053	(03/09)	G0G110	\$194
1241550	Ergotaminine (100 mg) (List Chemical)	G0B177	(03/09)	H0H017	\$194
1358503	Leuprolide Acetate (200 mg)	F0C430	(03/09)	G0H255	\$1,895
1410002	Methicillin Sodium (500 mg) (AS)	J0C333	(03/09)	K0H338	\$194
1471007	Norethynodrel (200 mg)	G	(03/09)		\$194
1604508	Rimantadine Hydrochloride (300 mg)	F0C266	(03/09)	G0H143	\$194
1651621	Delta-9-Tetrahydrocannabinol (1 mL)	F0G081	(03/09)	G0H324	\$226
1708773	Valsartan Related Compound A (10 mg)	G0G149	(03/09)	H1H329	\$775

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No Longer Valid as of April 30, 2009					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1009005	Acetylcysteine (200 mg)	H1B169 (04/09)	I0G320	\$194	
1030001	Amobarbital CII (200 mg)	F-2 (04/09)	F3G273	\$257	
1040708	Apigenin-7-glucoside (30 mg)	F (04/09)	G0H057	\$605	
1074007	Bisacodyl (125 mg)	I1B162 (04/09)	J0G408	\$154	
1078325	Bumetanide Related Compound A (10 mg)	G0F031 (04/09)	H0G264	\$605	
1082708	Butylated Hydroxytoluene (500 mg)	F0D122 (04/09)	F1G286	\$194	
1097104	Cefadroxil (200 mg)	I1B319 (04/09)	J0H018	\$194	
1098129	Ceftazidime, Delta-3-Isomer (10 mg)	H0E106 (04/09)	I0G189	\$605	
1134233	Citalopram Hydrobromide (125 mg)	F0F157 (04/09)	F1G292	\$349	
1242000	Erythromycin (250 mg)	M1E251 (04/09)	N0G117	\$194	
1242032	Erythromycin Related Compound N (50 mg)	F2A023 (04/09)	G0H032	\$605	
1270005	Fentanyl Citrate CII (100 mg)	K0C264 (04/09)	L0G319	\$299	
1302305	Halazepam CIV (200 mg) (AS)	F1C224 (04/09)	G0H075	\$257	
1303002	Haloperidol (200 mg)	I (04/09)	I1G285	\$194	
1319002	Hydrocortisone Hemisuccinate (200 mg)	I0D343 (04/09)	J0H091	\$194	
1370350	Lorazepam Related Compound D (25 mg)	G0A014 (04/09)	H0H002	\$605	
1396502	Methacrylic Acid Copolymer Type B (200 mg)	G0B141 (04/09)	H0G385	\$194	
1399001	Methamphetamine Hydrochloride CII (125 mg)	I (04/09)	I1G299	\$257	
1415006	Methotrimeprazine (200 mg)	F-2 (04/09)	F3G335	\$194	
1430305	Methyl Laurate (500 mg)	G0C356 (04/09)	H0H035	\$194	
1443307	Mezlocillin Sodium (350 mg)	G (04/09)	H0H213	\$194	
1444004	Minocycline Hydrochloride (200 mg)	I0C178 (04/09)	I1G208	\$194	
1457301	Naproxen (200 mg)	I-1 (04/09)	J0H044	\$194	
1463600	Nifedipine Nitrophenylpyridine Analog (25 mg)	K (04/09)	K1G378	\$605	
1477900	Octinoxate (500 mg) (Octyl Methoxycinnamate)	H0D213 (04/09)	I0G246	\$194	
1495005	Papain (1 g)	I1F174 (04/09)	J0H138	\$194	
1645006	Testolactone CIII (125 mg)	F-1 (04/09)	F2E319	\$206	
1653004	Theophylline (200 mg)	J0B180 (04/09)	J1H052	\$194	
1667406	Timolol Maleate (200 mg)	G-1 (04/09)	H0H046	\$194	



No Longer Valid as of May 31, 2009

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1020008	Aminobutanol (500 mg)	G-1 (05/09)	H0G256	\$484
1032007	Amphotericin B (125 mg)	J3C246 (05/09)	K0H185	\$154
1086301	Calcitriol (10 mg)	G0F104 (05/09)	H0H053	\$1,555
1091006	Capreomycin Sulfate (250 mg)	G1F191 (05/09)	H0H181	\$194
1134379	Clarithromycin (75 mg)	G0D356 (05/09)	G1G324	\$194
1154503	Cyclobenzaprine Hydrochloride (200 mg)	G0A013 (05/09)	H0G399	\$194
1235274	Enalaprilat (300 mg)	J0C268 (05/09)	J1G349	\$154
1392454	Meropenem (300 mg)	G0F100 (05/09)	H0G402	\$227
1448005	Morphine Sulfate CII (500 mg)	O0F186 (05/09)	P0H037	\$413
1460736	Nevirapine Related Compound B (15 mg)	F0D033 (05/09)	G0G271	\$605
1467804	Nizatidine (200 mg)	G (05/09)	H0G401	\$194
1472000	Norgestrel (125 mg)	J0C269 (05/09)	J1G387	\$154
1514008	Phenacetin Melting Point Standard (500 mg) (Approximately 135 degrees)	H3A009 (05/09)	I0H080	\$116
1546300	Polydimethylsiloxane (500 mg)	H0C020 (05/09)	I0G306	\$194
1559006	Prednisone (250 mg)	N0E330 (05/09)	O0G356	\$194
1592409	Quercetin (500 mg)	G0D407 (05/09)	H0G321	\$194
1667472	Tioconazole Related Compound C (25 mg)	G (05/09)	H0F262	\$605

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Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1012939	Allantoin (200 mg)	F0C169 (03/10)	G0H207	\$194
1044651	Atovaquone (200 mg)	F0B190 (03/10)	G0H328	\$194
1078766	Bupropion Hydrochloride Related Compound C (40 mg)	G0G006 (11/09)	G1H220	\$658
1110020	Chlordiazepoxide Related Compound A (25 mg)	G (03/10)	G1H228	\$605
1112503	Chlorobutanol (200 mg)	G1D301 (02/10)	H0H333	\$194
1134018	Ciclopirox (50 mg)	F0E086 (03/10)	G0G398	\$194
1137005	Clindamycin Palmitate Hydrochloride (500 mg)	G0D334 (03/10)	H0I037	\$532
1173235	Desogestrel (50 mg)	G1F145 (03/10)	H0H041	\$194
1173508	Desoximetasone (200 mg)	H0B036 (02/09)	H1H451	\$194
1187003	Dibucaine Hydrochloride (500 mg)	I (01/10)	J0I022	\$194
1270446	Fexofenadine Related Compound C (15 mg) (AS)	F0E291 (10/09)	G0I059	\$605
1287030	Furosemide Related Compound B (100 mg)	J0E326 (03/10)	K0H287	\$605
1291559	Ginkgo Terpene Lactones (50 mg)	F0G080 (12/09)	G0I051	\$399
1292336	Glimepiride Related Compound C (20 mg)	F0E234 (03/10)	F1H423	\$605
1304005	Heparin Sodium (10 x 1 mL)	L0G091 (03/10)	L1I033	\$194
1356971	Letrozole (200 mg)	F0B170 (03/10)	G0H299	\$194
1370360	Lorazepam Related Compound E (25 mg)	H0D254 (03/10)	I0H446	\$605
1424007	Methyclothiazide (200 mg)	G (03/10)	G1H341	\$194
1430509	3-O-Methylmethyldopa (50 mg)	G-1 (03/10)	H0H391	\$605
1499414	Paricalcitol Solution (3 mL)	G0H292 (03/10)	G1I063	\$310
1546922	Polyethylene Terephthalate G (PETG) (3 Strips)	F (03/10)	F1H430	\$194
1557000	Prednisolone Sodium Phosphate (500 mg)	F0E300 (02/10)	F1H347	\$194
1621008	Stearic Acid (500 mg)	J1D360 (03/10)	J2G054	\$194
1632004	Sulfanilamide (5 g)	O0B047 (03/10)	O1H320	\$194
1673828	Trenbolone Acetate CIII (200 mg)	F0D390 (12/07)	G0I045	\$206
1683504	Trientine Hydrochloride (200 mg)	F2B257 (12/09)	G0H377	\$194
1686309	Trifluridine (200 mg)	F (02/10)	G0I041	\$224
1700501	L-Tryptophan (200 mg)	G2E237 (03/10)	H0H122	\$194
1717708	Vitexin (25 mg)	F0C142 (01/10)	G0I046	\$647



USP Publication Highlights

	<p>USP 32–NF 27 is official May 1, 2009! Order today and be prepared</p> <p>Make sure you have new and revised <i>USP–NF</i> standards that become official May 1, 2009. <i>USP 32–NF 27</i> through the <i>Second Supplement</i> contains significant new information: more than 300 new and revised monographs and 26 new and revised General Chapters! Order now at www.usp.org/products/USPNF or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>
	<p>Just Published—2009 USP Dictionary with more than 4,500 updates!</p> <p>The new <i>USP Dictionary of USAN and International Drug Names</i> published April 1. Features includes significant updates for generic and brand drug names, pronunciations, chemical structures, UNII codes, and more. Available in print and online formats. To order, visit www.usp.org/products/dictionary or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>
	<p>New USP Dietary Supplements Compendium—Save \$50 through June 15!</p> <p>The new <i>USP Dietary Supplements Compendium (DSC)</i>, publishing in the spring, combines <i>USP–NF</i> standards with information from <i>the Food Chemicals Codex, Sixth Edition</i>; regulatory and industry documents; and helpful tools and resources. The <i>DSC</i> will be published every two years in hardcover print, English only. Order through June 15, 2009, for only \$375 (regular price is \$425)! Visit www.usp.org/products/dietarySupplementsCompendium/ or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>
	<p>First Supplement to Food Chemicals Codex, Sixth Edition, has published—Subscribe now!</p> <p>The <i>First Supplement to the Food Chemicals Codex (FCC), Sixth Edition</i>, recently published, providing important updates to <i>FCC</i> standards of purity and quality for food ingredients. The <i>FCC</i> is published every two years with <i>Supplements</i> provided between editions. Available in print and new online formats, in English only. To subscribe, visit www.usp.org/products/FCC/ or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>

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Event Highlights

USP Customer Days—Coming to a City Near You!

The USP Account Management Team is traveling across the U.S. and Canada holding free seminars to discuss USP publications, Reference Standards, USP Verified Services, Pharmacopeial Education, new initiatives, and scientific hot topics.

The next meeting is scheduled for Rockville, MD (May 11, 2009). Registration and more information are available at www.usp.org/products/USPCustomerDays/ or contact: uspcustomerday@usp.org



Hot Topic Meetings

Metal Impurities (April 28–29) [Learn More](#)

Adulteration of Food Protein - The Need for New Prevention Strategies (June 16 -17, 2009) [Learn More](#)

Enzymes (July 8-9, 2009): [Register](#)

Excipients (July 20-21, 2009) [Learn More](#)

Bioassays (August 12-13, 2009) [Learn More](#)

Topical Dermal Dosage Forms Workshop (September 14-15, 2009)

Pharmacopeial Education

View the Latest USP Pharmacopeial Education Online Catalog—

www.uspeducation.com

Get details on current and upcoming education offerings, including on-demand online courses, classroom lectures, and lab training. Updated throughout the year, this convenient online catalog provides click-through links for registration, instructor information, and related products.

Featured Courses

Dissolution: Theory and Best Practices

USP is offering this popular course in two configurations: as a lecture and as a lecture and lab. Both formats provide focused, relevant instruction on the fundamentals of pharmaceutical dissolution testing as described in USP General Chapter <711> and gain an overview of the theory, practice, and history of dissolution. In the lab session, you will also learn the practical aspects of conducting dissolution tests, best practices, and performance verification testing.

One Day—Classroom Lecture Only: US \$695

May 5, 2009; Distek Headquarters, Somerset, NJ

[Click here](#) to register.

Two Day— Classroom Lecture and Lab: US \$1,495

May 5–6, 2009; Distek Headquarters, Somerset, NJ

[Click here](#) to register.





Good Weighing Practices in the Pharmaceutical Industry: A Risk-Based Guideline

This unique course, developed in conjunction with Mettler-Toledo, provides an in-depth look at the factors that contribute to weighing uncertainty as well as practical advice on how to avoid common mistakes in the lab. You will learn about balance selection, apparatus use, and maintenance testing programs.

Classroom Lecture: US \$795

May 19, 2009, Basel, Switzerland

June 2, 2009; San Francisco, CA

June 4, 2009, Somerset, NJ

[Click here](#) to register.

Fundamentals of Bioassay Practices

Gain insight into the fundamentals of bioassay practices and principles necessary to implement the guidance outlined in *USP* chapters. This unique course provides discussion on statistical and assay design, analysis, and validation to help scientists develop and perform bioassays. Visit http://www.usp.org/education/pe/courses.html?course_id=175 to obtain details of special offers and group discounts.

Classroom Lectures: US \$595 (Special offers and group discounts available)

August 11; Rockville, MD, USA

[Click here](#) to register.

On-demand Module 1 and 2 for “Developing Compendial HPLC Practices” are Now Available! (\$149 each)

Module 1 provides an introduction to the basic concepts, calculations, and underpinnings of high performance liquid chromatography (HPLC) as applied in everyday practice for quality control and assurance in the pharmaceutical industry. Module 2 covers equipment components, practical considerations, trouble-shooting and issues related to USP and HPLC such as definitions, types of tests and calculation of results for monographs.

[Click here](#) to register.

Upcoming PE Courses Worldwide—click on link for dates and details

- [Advanced Dissolution](#)
- [Aseptic Processing and Compliance Tools for USP <797>](#)
- [Dissolution: Theory and Best Practices](#)
- [Validation of Compendial Procedures](#)

Subscribe to the Pharmacopeial Education Email Bulletin

USP Pharmacopeial Education is developing several new courses for introduction in 2009. If you would like to stay informed of our new curriculum and upcoming schedule, [subscribe now](#) to the Pharmacopeial Education Bulletin.



Compendial Highlights

Call for Candidates—Council of Experts and expert committees

SCIENCE • INNOVATION • PASSION • COMMITMENT—YOU set the Standard
Volunteers on the Council of Experts, Expert Committees, and Expert Panels are an integral part of the USP standards–setting process. Participation as a volunteer expert affords you the unique opportunity to

- Influence Drug Quality
- Utilize Your Expertise
- Advance Your Profession
- Improve Public Health

USP invites qualified candidates—pharmaceutical scientists, academicians, regulatory professionals, healthcare professionals, and others—to apply to serve as scientific decision makers on the Council of Expert Committees. The 2010–2015 Council of Experts includes 20 Expert Committees in the areas of Nomenclature, Small Molecules, Biologics and Biotechnology, Excipients, General Chapters, Reference Standards, Compounding, Food Ingredients, and Dietary Supplements, with each member of the Council of Experts chairing an Expert Committee. USP is also seeking qualified candidates for its Expert Panels, which play an important advisory role to the Council of Experts. [Learn More](#)

Monograph Redesign—USP has received more than 2400 comments and is continuing the comment review process. Although the deadline has passed for comments to be included in *USP 33–NF 28*, you can still comment on the proposed design changes for *USP–NF* monographs. The comments received will be considered for Errata. This is your chance to become familiar with the new formats and identify any errors that may have been introduced through the conversion of the monographs to this new style. The new format will be incorporated in *USP 33–NF 28*. Click [here](#) for more details.

Website Redesign—USP launched a redesigned and reorganized USP–NF section of its public Web site, USP.org. These changes were part of an effort to separate official text from general announcements, streamline and clarify the Accelerated Revision Processes, improve general navigation of this section, and make finding Stimuli articles and Web pages related to the USP–NF more user-friendly. This upgrade implemented a number of enhancements click [here](#) for details.



New Official Text

Revision Bulletins:

[Propofol Injectable Emulsion](#) (03/27/09)

[Rocuronium Bromide](#) (03/27/09)

[Powdered Ginkgo Extract Monograph](#) (02/27/09)

[Terbinafine Hydrochloride Monograph](#) (02/27/09)

[Glycerin Monograph](#) (02/04/09) — [Versión en español](#) (30KB) (03/06/09)

IRAs (Pharmacopeial Forum 35(2) March-April 2009)

[Galantamine Tablets](#) (104KB) (02/27/09)

Errata

Vol. 35, No. 2 [March–April 2009] (63KB) (02/27/09)

Compendial Notices

General Announcements: [Amended USP 32-NF 27 Commentary](#) (03/19/09)

Intent to Revise: [Nefazodone Hydrochloride](#) (03/20/09)

General Chapter Status

The [General Chapters status page](#) provides users with the status of General Chapter revisions. The status is revised every other month to coincide with the Pharmacopeial Forum publication schedule.

Sign up to receive Updates electronically at

<http://www.usp.org/support/products/uspNewslettersRequest.html?promo=compendial>

Stimuli Articles

Featured in *PF* 35(2), March–April 2009

[A Discussion of Net Water Gain for Water Vapor Transmission Rate Determinations](#) (535KB)



Tip of the Month

Are you interested in Heavy Metals <231>? Please read below for information on an important upcoming workshop.

Workshop on Metals in Pharmaceuticals, Foods and Dietary Supplements

April 28 – 29, 2009

USP Headquarters, Rockville, Maryland

Overview

Metal impurities tests have been available in the United States Pharmacopeia—National Formulary for many years. These tests include the general heavy metals screening tests contained in General Chapter <231> Heavy Metals, as well as specific tests for aluminum, arsenic, iron, lead, mercury and selenium. The screening tests in <231> are non-element-specific limit tests and apply to a relatively small number of elements.

The purpose of the Metal Impurities Workshop is to engage in dialog to develop new approaches for metal impurities in pharmaceuticals and dietary supplements, including methodologies and toxicological limits. These new approaches are intended to replace the existing methods in General Chapter <231> Heavy Metals. This public workshop will seek constructive input from a wide range of stakeholders and seek common ground on general approaches to the standard. The workshop topics will cover: Definition and Scope of the Metal Impurities Activities, Metal Impurity Toxicology Limits, Metal Impurity Methodology and Risk Assessment and Implementation.

For more information and to register please visit

<http://www.usp.org/meetings/workshops/metalImpuritiesWorkshop.html>

Question of the Month

How do the <467> requirements apply to animal health items, if at all?

The <467> requirements apply to items for veterinary use. However, the current limits are based on human use and limits for different species of animals probably would need to be different. [Frequently Asked Questions about <467> Residual Solvents](#)

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