



February 2013

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## 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 January 2013; backordered items with estimated availability dates; items that have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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](http://www.usp.org/products).

A list of [USP Reference Standards Under Development](#) that we expect to release within six months has been posted. The list is organized by calendar quarter, and can be downloaded as an MS Excel (xls) spreadsheet. It will be updated four times a year.

**The Reference Standards Release Notification Service** can be used to notify you when a new never-before-released Reference Standard becomes available. The Notification Service does not communicate the release of back-ordered items or lot changeovers. To participate, fill out the form online at [www.usp.org/reference-standards/find-reference-standard/notification-service](http://www.usp.org/reference-standards/find-reference-standard/notification-service).

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## New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1029308	Amlexanox	200 mg	F0K322	\$210
1044200	Astaxanthin (Synthetic)	3 X 30 mg	F0K346	\$210
1118350	Chloroquine Related Compound D	15 mg	F0L546	\$655
1309911	Powdered Holy Basil Extract	1 g	F0L561	\$210
1347880	Isobutyraldehyde	3 X 1.2 mL	F0L075	\$210
1380502	Memantine Hydrochloride	150 mg	F0L377	\$210
1380546	Memantine Related Compound D	50 mg	F0L054	\$655
1380557	Memantine Related Compound E	15 mg	F0L578	\$655
1681815	Triclocarban Related Compound A	15 mg	F0L532	\$655
1681845	Triclocarban Related Compound C	15 mg	F0L479	\$655

## Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1604803	Ritonavir	200 mg	G0L143	\$210

## Backorder Availability Estimates, February 11, 2013

Catalog #	Description	Expected Availability*
1044550	Atorvastatin Related Compound D (20 mg)	Q1/13
1061005	Benzotropine Mesylate (200 mg)	Q2/13
1096804	Cathinone Hydrochloride CI (50 mg) (alpha-Aminopropiophenone Hydrochloride)	Q3/13
1273003	Fludrocortisone Acetate (250 mg)	Q1/13
1301801	Guanethidine Monosulfate (200 mg)	Q1/13
1358810	Levalbuterol Related Compound C (30 mg)	Q1/13
1381742	Menthyl Anthranilate (500 mg/ampule) (Meradimate)	Q1/13
1478130	Oleic Acid (1 g)	Q1/13
1478844	Orlistat Related Compound D (10 mg)	Q1/13
1612947	Beta-Sitosterol (300 mg)	Q2/13
1643543	Temozolomide (200 mg)	Q1/13

\*Dates are targets and may change at any time. Q1/13 January–March 2013; Q2/13 April–June 2013; Q3/13 July–September 2013

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## Items with New Package Size or New Description

Catalog #	Description	Old Size	Size	Lot	Price (USD)
1287722	Galactosamine Hydrochloride	300 mg	50 mg	G0L378	\$210
1295516	Glyburide Related Compound A*	25 mg	25 mg	F1L307	\$655
1460736	Nevirapine Related Compound B	15 mg	10 mg	I0L362	\$655

\*The chemical name of this item has changed from 5-chloro-2-methoxy-N-[2-(4-sulfamoylphenyl)ethyl]benzamide to 4-[2-(5-chloro-2-methoxybenzamido)ethyl]benzenesulfonamide

## RS Lots That are No Longer Valid

These Tables list 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 Store online [here](#) using the Reference Standards: Alphabetical Listings to look up the item of interest.

No Longer Valid as of January 31, 2013					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1012553	Albendazole (200 mg)	H0E240 (01/13)	H1K275	\$210	
1018505	Amantadine Hydrochloride (200 mg)	H1D207 (01/13)	I0J377	\$210	
1034002	Amprolium (200 mg)	G0C317 (01/13)	H0K314	\$210	
1046090	Azithromycin N-Oxide (15 mg)	F0G119 (01/13)	F1K426	\$655	
1047503	Bacitracin (1 g) (Susceptibility disk standard)	H0H096 (01/13)	I0K222	\$210	
1048630	Benazepril Related Compound B (15 mg)	H0I343 (01/13)	I0K261	\$655	
1097782	Cefmetazole (200 mg)	G0E260 (01/13)	H0K343	\$210	
1134299	Citalopram Related Compound F (200 mg)	F0F169 (01/13)	F1K331	\$655	
1181302	Dextrose (500 mg)	J2E294 (01/13)	K0K311	\$210	
1224620	Docosahexaenoic Acid Ethyl Ester (500 mg)	F0H167 (01/13)	G0K228	\$568	
1285931	Fluvastatin Sodium (350 mg)	H0I353 (01/13)	I0K242	\$279	
1302101	Guanfacine Hydrochloride (125 mg)	G1F063 (01/13)	H0K209	\$167	
1302509	Halcinonide (200 mg)	G0G239 (01/13)	H0L014	\$210	
1317302	Hydrocortisone Butyrate (200 mg)	I0G158 (01/13)	J0K395	\$210	
1347642	Irinotecan Related Compound C (10 mg)	F0I280 (01/13)	G0K219	\$655	
1370338	Lorazepam Related Compound B (25 mg)	H0J044 (01/13)	I0K255	\$655	
1391000	3-Mercapto-2-methylpropanoic Acid 1,2-Diphenylethylamine Salt (75 mg)	G (01/13)	H0L022	\$655	
1546707	High Density Polyethylene (3 strips)	H0F046 (01/13)	I0K217	\$210	
1548101	Potassium Benzoate (1 g)	F0D161 (01/13)	F1K362	\$210	
1597005	Quinine Sulfate (500 mg)	I0E071 (01/13)	J0K293	\$210	
1604858	Rivastigmine Tartrate (200 mg)	F0I281 (01/13)	G0K328	\$568	
1615956	Sorbic Acid (1 g)	F0D129 (01/13)	G0K313	\$210	
1656002	Thiamine Hydrochloride (500 mg) (Vitamin B1 Hydrochloride)	O1F236 (01/13)	P0K366	\$210	
1696007	Tripolidine Hydrochloride (300 mg)	I (01/13)	I1K365	\$210	
1705800	Uracil Arabinoside (50 mg)	H0F084 (01/13)	I0J418	\$210	
1709018	Vancomycin B with Monodechlorovancomycin (300 mg)	F1I232 (01/13)	F2K018	\$655	
1714506	Vinorelbine Tartrate (200 mg)	F2E197 (01/13)	G0K223	\$2,028	



No Longer Valid as of February 28, 2013				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1134368	Citric Acid (200 mg)	G0F161 (02/13)	H0K310	\$210
1144000	Codeine Phosphate <b>CII</b> (100 mg)	K0G040 (02/13)	L0K249	\$278
1162320	Dacarbazine Related Compound A (50 mg)	H0C052 (02/13)	H1K145	\$655
1235503	Endotoxin (10,000 USP Endotoxin Units) (COLD SHIPMENT REQUIRED)	G3E069 (02/13)	H0K354	\$210
1235820	Enoxaparin Sodium (300 mg) (COLD SHIPMENT REQUIRED)	F0I110 (02/13)	G0L137	\$210
1254009	Estradiol Valerate (100 mg)	L1D286 (02/13)	L2L009	\$210
1268808	Etoposide (300 mg)	H0C315 (02/13)	H1K394	\$210
1270355	Ferrous Sulfate (1.5 g)	F0D196 (02/13)	F1K388	\$210
1359426	Levetiracetam Related Compound A (20 mg)	F0H173 (02/13)	G0K335	\$655
1372050	Lysophosphatidylcholine (250 mg) (INTERNATIONAL COLD CHAIN SHIPMENT REQUIRED)	F0H229 (02/13)	G0K005	\$256
1478119	Ofloxacin Related Compound A (25 mg)	F0E276 (02/13)	G0K034	\$655
1478822	Orlistat Related Compound B (10 mg)	F0G161 (02/13)	G0K407	\$655
1581005	Pseudoephedrine Hydrochloride (125 mg) ( <b>List Chemical</b> )	J1B203 (02/13)	J2K305	\$167
1604814	Ritonavir Related Compounds Mixture (50 mg)	F0F058 (02/13)	F1K283	\$655
1625009	Sulfadiazine (200 mg)	J1G290 (02/13)	K0K193	\$210
1631500	Sulfamethoxazole N4-glucoside (25 mg)	H1D290 (02/13)	I0K227	\$655
1642212	Sumatriptan Succinate Related Compound A (15 mg)	I0I220 (02/13)	J0K317	\$838

No Longer Valid as of March 31, 2013				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1033407	Ampicillin Trihydrate (200 mg)	H0H346 (03/13)	H1L041	\$210
1046001	Azathioprine (200 mg)	H1H303 (03/13)	I0J145	\$210
1048620	Benazepril Related Compound A (25 mg)	G0F352 (03/13)	H0K411	\$655
1134404	Clavam-2-carboxylate Potassium (3.4 ug)	J0I149 (03/13)	K0J282	\$655
1225703	Doxorubicin Hydrochloride (50 mg)	K1G106 (03/13)	L0K258	\$644
1260012	Ethinyl Estradiol Related Compound A (20 mg)	I0J071 (03/13)	J0K316	\$655
1265515	Ethylene Glycol (0.5 mL)	F0G403 (03/13)	G0K011	\$210
1319002	Hydrocortisone Hemisuccinate (200 mg)	J0H091 (03/13)	K0K423	\$210
1356734	Lactic Acid (1.5 mL/ampule; 3 ampules)	F0D027 (03/13)	G0L178	\$210
1358004	Leucovorin Calcium (500 mg)	K0F033 (03/13)	K1K334	\$216
1370000	Loperamide Hydrochloride (200 mg)	H0C202 (03/13)	H1L093	\$210
1380105	Melatonin (150 mg)	F0E027 (03/13)	G0K239	\$222
1478323	Olanzapine Related Compound B (15 mg)	F0H160 (03/13)	G0K318	\$655
1553768	Pramipexole Related Compound A (15 mg)	F0J114 (03/13)	G0L086	\$655
1601102	Residual Solvents Mixture - Class 1 (1.2 mL/ampule; 3 ampules)	F1H387 (03/13)	G0K378	\$210
1643408	Temazepam <b>CIV</b> (200 mg)	H1G187 (03/13)	I0L082	\$278
1672600	Tramadol Hydrochloride (100 mg)	F0H020 (03/13)	G0L065	\$210
1702008	Tubocurarine Chloride (175 mg)	K-1 (03/13)	L0L470	\$210
1711304	Verapamil Related Compound A (50 mg)	H (03/13)	I0J297	\$655
1033407	Ampicillin Trihydrate (200 mg)	H0H346 (03/13)	H1L041	\$210



## Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1017502	Dried Aluminum Hydroxide Gel (200 mg)	G0I104 (01/14)	H0M005	\$210
1050905	Benzaldehyde (2 x 1 mL) <b>(List Chemical)</b>	G0K197 (01/14)	H0L174	\$210
1075203	Bis(2-ethylhexyl)maleate (2 g)	H0J224 (02/14)	H1K384	\$655
1091040	Caprylic Acid (300 mg)	F0D378 (01/14)	F1L115	\$210
1091108	Capsaicin (100 mg)	H0G235 (01/14)	I0L046	\$210
1097636	Cefepime Hydrochloride (500 mg)	H0G278 (01/14)	I0L200	\$210
1111001	Chlorhexidine (200 mg)	F0C306 (01/14)	G0L171	\$210
1134379	Clarithromycin (100 mg)	G2I235 (01/14)	H0H380	\$210
1180004	Dextroamphetamine Sulfate <b>CII</b> (500 mg)	I1F106 (01/14)	J0L459	\$291
1225281	Dorzolamide Hydrochloride (200 mg)	G0E278 (01/14)	H0L259	\$210
1235300	Enalapril Maleate (200 mg)	J1C267 (01/14)	K0L429	\$210
1242021	Erythromycin C (50 mg)	F-3 (02/14)	F4L354	\$655
1270005	Fentanyl Citrate <b>CII</b> (100 mg)	L0G319 (02/14)	M0L328	\$323
1270399	Fexofenadine Related Compound B (25 mg)	F0D246 (01/14)	G0L338	\$655
1287722	Galactosamine Hydrochloride (50 mg)	F0G137 (01/14)	G0L378	\$210
1295516	Glyburide Related Compound A (25 mg)	F0E224 (02/14)	F1L307	\$655
1353102	Diluted Isosorbide Mononitrate (750 mg)	F0G155 (01/14)	G0L461	\$210
1356734	Lactic Acid (1.5 mL/ampule; 3 ampules)	F1K398 (01/14)	G0L178	\$210
1356836	Lamivudine (200 mg)	H0I378 (01/14)	H1L282	\$210
1379060	Mefloquine Related Compound A (20 mg)	F0E166 (01/14)	F1L551	\$655
1394008	Mestranol (200 mg)	K0C065 (01/14)	K1M025	\$210
1396309	Metformin Hydrochloride (200 mg)	I0H236 (01/14)	J0L465	\$246
1441298	Metoprolol Succinate (200 mg)	G0F179 (01/14)	H0L334	\$210
1444707	Mitomycin (50 mg)	K (01/14)	L0L428	\$644
1448606	Moxifloxacin Hydrochloride (200 mg)	F0H454 (01/14)	G0L202	\$557
1460736	Nevirapine Related Compound B (10 mg)	H0J192 (01/14)	I0L362	\$655
1478334	Olanzapine Related Compound C (5 mg) (INTERNATIONAL COLD CHAIN SHIPMENT REQUIRED)	G0K178 (01/14)	H0L545	\$655
1494909	Pantoprazole Related Compound A (25 mg)	G0J267 (01/14)	H0L544	\$655
1578554	Prostaglandin B1 (25 mg) ((13E,15S)-15-Hydroxy-9-oxoprostanoic acid)	F0E022 (12/13)	G0M011	\$1,683
1604803	Ritonavir (200 mg)	F0F049 (10/13)	G0L143	\$210
1643419	Telmisartan (200 mg)	F0I345 (01/14)	G0L274	\$210
1667701	Alpha Tocopheryl Acetate (250 mg) (Vitamin E Acetate)	K (01/14)	L0K188	\$210
1705006	L-Tyrosine (500 mg)	K1I093 (02/14)	L0L199	\$210
1709018	Vancomycin B with Monodechlorovancomycin (300 mg)	F2K018 (01/14)	F3L348	\$655

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## USP Publication Highlights

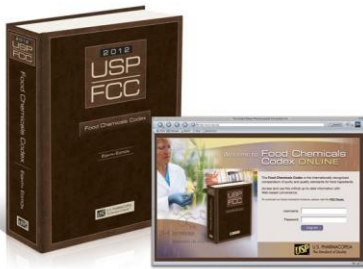


### Be Prepared for Compliance—Order **USP 36–NF 31** Today!

The 2013 edition of *USP–NF* becomes official May 1. Order today for access to important updates, including:

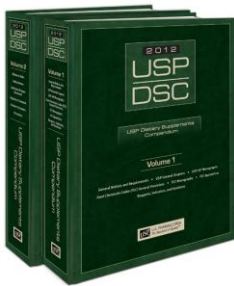
- New General Chapters: <17> Prescription Container Labeling, <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients, and <1761> Applications of Nuclear Magnetic Resonance Spectroscopy
- Revised General Chapters: <788> Particulate Matter in Injections, <921> Water Determination, and <1136> Packaging—Unit of Use
- 89 new and revised monographs

Available in print, online, and USB flash drive formats. Subscribe today at <http://uspgo.to/USPNF-2013> 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).



### New **Food Chemicals Codex (FCC), Eighth Edition**.

The *FCC, Eighth Edition*, features more than 1,100 monographs, appendices with step-by-step methods, and helpful information for manufacturers, suppliers, and users of food ingredients—including data from the recently updated USP Food Fraud Database. Subscription includes the main edition plus three supplements that publish at six-month intervals. The first supplement became effective Dec. 1, 2012. The second supplement publishes Mar. 1, 2013, and becomes effective June 1, 2013. It includes 15 new monographs! Print and online formats. Order at <http://uspgo.to/food-chemicals-codex> 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).



### New **2012 Dietary Supplements Compendium (DSC)—Two-Volume Set Available Now!**

The recently updated *DSC* has 64 new dietary supplement monographs, 23 Admissions Criteria Safety Reviews, Guidance Documents, ~330 pages of full-color illustrations/images, and more. Order at [www.usp.org/store/products-services/dietary-supplements-compedium](http://www.usp.org/store/products-services/dietary-supplements-compedium) 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).

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## Event Highlights

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### **USP User Forums Coming to a City Near You!**

The USP Account Management Team will be traveling around the world holding free seminars to discuss timely USP initiatives and how to use available USP resources to your advantage.

More information including locations and dates is available [here](#), or contact [USPUserForum@usp.org](mailto:USPUserForum@usp.org).

### **Workshops**

USP web forums and workshops encourage discussion of a wide range of current scientific findings and regulatory trends. Participants discuss hot topics that concern the public and exchange practical advice.

Information on workshops is available [here](#).

## Pharmacopeial Education

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USP's Pharmacopeial Education division is dedicated to providing quality education for chemists, scientists, and healthcare practitioners in the United States and around the world. We seek to improve the effective implementation of standards that affect best practices for the development, manufacture, regulation, compounding, storage, and dispensing of pharmaceuticals, dietary supplements, food additives, and other therapeutics.

To find a course, please visit [www.usp.org/education/pe/courses.html](http://www.usp.org/education/pe/courses.html)

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## Compendial Highlights

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### New Official Text



#### Revision Bulletins:

[Cetirizine Hydrochloride Tablets](#) (posted 31–Jan–2013; official 01–Feb–2013)  
[Divalproex Sodium Extended-Release Tablets](#) (posted 31–Jan–2013; official 01–Feb–2013)  
[Insulin](#) (posted 31–Jan–2013; official 01–Feb–2013)  
[Levetiracetam Oral Solution](#) (posted 31–Jan–2013; official 01–Feb–2013)  
[Oxcarbazepine Oral Suspension](#) (posted 31–Jan–2013; official 01–Feb–2013)  
[Tacrolimus Capsules](#) (posted 31–Jan–2013; official 01–Feb–2013)  
[Verapamil Hydrochloride Extended-Release Tablets](#) (posted 31–Jan–2013; official 01–Feb–2013)  
[<232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures](#) (posted 28–Jan–2013; official 01–Feb–2013)



#### IRAs

[Heparin Lock Flush Solution](#) (posted 31–Jan–2013; official 01–May–2013)  
[Heparin Sodium Injection](#) (posted 31–Jan–2013; official 01–May–2013)  
[Sevoflurane](#) (posted 31–Jan–2013; official 01–Mar–2013)  
[Tramadol Hydrochloride](#) (posted 31–Jan–2013; official 01–Mar–2013)



#### Access new USP–NF Errata



#### New Stage 6 Notices

[Butylparaben](#) (posted 30–Nov–2012; official 01–Dec–2013; updated 11–Jan–2013)

### Compendial Notices

#### New

[Call for Candidates: Intentional Adulteration of Dietary Supplements with Drugs Expert Panel](#) (posted 08–Feb–2013; deadline 15–Mar–2013)  
[General Notices and Requirements: Summary of Proposed Changes](#) (posted 28–Dec–2012; **updated 04–Feb–2013**)  
[USP 36–NF 31, First Supplement Commentary](#) (posted 01–Feb–2013)  
[Complete Reagent Section No Longer Being Printed in Supplements to USP–NF](#) (posted 01–Feb–2013)  
[Prescription/Nonprescription Stakeholder Forum Scheduled for June: Agenda Topics Sought](#) (posted 31–Jan–2013; deadline 30–Apr–2013)  
[<232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures Revision Bulletin](#) (posted 28–Jan–2013)  
[Call for Candidates: Pharmaceutical Compounding—Sterile Preparations Expert Panel](#) (posted 11–Jan–2013; deadline 01–Mar–2013)

Sign up to receive updates electronically at [www.usp.org/support-home/opt-information-service](http://www.usp.org/support-home/opt-information-service).

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## [Stimuli Articles](#)

Featured in *PF 39(1)*, January–February 2013

- Elemental Impurities in Pharmaceutical Waters
- Public Documentary Standards and Reference Materials
- Responses to Public Comments about the Introduction of General Chapter Inhalation and Nasal Drug Products—General Information and Product Quality Tests <5> and Revisions to General Chapter Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers <601>
- USP's Monographs in Support of FDA's OTC Monograph System: Modernization Opportunities

## Tip of the Month

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To help ensure the quality of popular food ingredients increasingly being incorporated into products sold in the United States and worldwide, standards for omega 3-rich krill oil and natural, low-calorie stevia sweeteners are among the latest proposed revisions to the *Food Chemicals Codex (FCC)*. Manufacturers and other parties are encouraged to comment on these proposals, which are contained in the most recent *FCC Forum* ([www.usp.org/fcc/fccForum.html](http://www.usp.org/fcc/fccForum.html))—the free, online vehicle for public review and comment on draft *FCC* standards. The proposed standards are available for public review for a 90-day comment period, which closes March 31, 2013. To make comments, go to [www.usp.org/fcc/fccForum.html](http://www.usp.org/fcc/fccForum.html)

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## Question of the Month

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I am having trouble purchasing a packed GC column that meets the specifications listed in the monograph. Can I use a capillary column instead?

You may use a capillary column based on the information in section 6.30 of the *USP-NF General Notices* where it states:

### 6.30. Alternative and Harmonized Methods and Procedures

Alternative methods and/or procedures may be used if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, or in other special circumstances. Such alternative procedures and methods shall be validated as described in the general chapter Validation of Compendial Procedures < 1225 > and must be shown to give equivalent or better results. Only those results obtained by the methods and procedures given in the compendium are conclusive.

The use of a capillary column would be considered an alternate procedure and you would have to determine what column would be acceptable.

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