



URGENT RECALL-RETAIL LEVEL

Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10/500mg

December 6, 2012

Dear Sir / Madame:

Please be advised that the following product, Hydrocodone APAP 10/500, manufactured by Qualitest Pharmaceuticals is being recalled to the **RETAIL LEVEL**. This recall affects the following NDC numbers and any lot associated with these NDC numbers beginning with the with the letter "C". A comprehensive listing of the lot numbers is provided as Attachment 1 to this recall notice.

Affected NDC Numbers/Bottle Counts:

NDC Number	Bottle Count
0603-3888-16	30
0603-3888-20	60
0603-3888-02	90
0603-3888-21	100
0603-3888-22	120
0603-3888-26	150
0603-3888-04	180
0603-3888-28	500
0603-3888-32	1000

Reason For Recall - It is possible that a small number of tablets from the affected lots may exceed the weight requirement and could exceed the label claim potency requirements for the ingredients of hydrocodone bitartrate and acetaminophen.

RECALL INSTRUCTIONS:

1. Please examine your stock immediately to determine if you have any product as described above. If so, immediately discontinue distribution and/or dispensing. The affected product lots were distributed between February 20, 2012 and November 19, 2012.
2. **Pharmacists, in order to make your patients aware of the recall, please post the enclosed press release.**
3. Wholesale distributors, notify any customers or sub accounts who may have received this product from you to examine their stock, and request they return any affected product directly to CLS MedTurn.
4. We request you immediately complete and return the included "Recall Response Form" to CLS MedTurn. Upon receipt, a return kit will be sent to you including return authorization label(s) and return instructions.

This recall is being conducted with the knowledge of the U.S. Food & Drug Administration.

We apologize for the inconvenience, and thank you in advance for your cooperation as well as your continued support of Qualitest.

Sincerely,

Larry Kass
Dir. Third Party Quality
Qualitest



Attachment 1: Lot Number Listing for Recalled Lots

PRODUCT DESCRIPTION	NDC NUMBER	LOT #	EXP DATE
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C1110412B	13-Dec
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C1530512A	13-Dec
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C1151012B	13-Dec
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C1160712B	13-Dec
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C0950812B	13-Dec
HYDROCODONE APAP 10/500 C3 180 count	0603-3888-04	C1110412C	13-Dec
HYDROCODONE APAP 10/500 C3 180 count	0603-3888-04	C0950812A	13-Dec
HYDROCODONE APAP 10/500 C3 30 count	0603-3888-16	C1160712C	13-Dec
HYDROCODONE APAP 10/500 C3 60 count	0603-3888-20	C1160712A	13-Dec
HYDROCODONE APAP 10/500 C3 60 count	0603-3888-20	C1110412A	13-Dec
HYDROCODONE APAP 10/500 C3 60 count	0603-3888-20	C0930812A	13-Dec
HYDROCODONE APAP 10/500 C3 60 count	0603-3888-20	C1141012B	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0740312A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0890812A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0560212A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0780112C	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0790112C	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0910812A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0550212A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0870812A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0880812A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1121012A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1560512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0730112B	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0760112A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1540512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1131012A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0950412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1030412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0720312A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1510512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0740112B	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0900812A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0730312A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0970412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0750112A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0980412A	13-Dec



PRODUCT DESCRIPTION	NDC NUMBER	LOT #	EXP DATE
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0770112C	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1050412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1570512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1450512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1111012A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0540212A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1140412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0710312A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1460512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1440512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1130412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0960412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1060412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1550512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1040412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1070412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1071012A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1470512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1061012A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1520512A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1081012A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1101012A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1120412A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0920812A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0860812A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1141012A	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1530512B	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1160712D	13-Dec
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0950812D	13-Dec
HYDROCODONE APAP 10/500 C3 120 count	0603-3888-22	C0680312A	13-Dec
HYDROCODONE APAP 10/500 C3 120 count	0603-3888-22	C0670312A	13-Dec
HYDROCODONE APAP 10/500 C3 120 count	0603-3888-22	C0930812B	13-Dec
HYDROCODONE APAP 10/500 C3 120 count	0603-3888-22	C0950812C	13-Dec
HYDROCODONE APAP 10/500 C3 150 count	0603-3888-26	C1160712E	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1500512A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1180712A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1080412A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1020412B	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0700312A	13-Dec



PRODUCT DESCRIPTION	NDC NUMBER	LOT #	EXP DATE
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0960812A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1010412B	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0690312A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1480512A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0940812A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0720112B	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1090412A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1490512A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1170712A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0630212B	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0640212B	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1100412A	13-Dec
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0941112A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0750312A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0570212B	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0760312A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0970812A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0580212B	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0610212A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0600212A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0620212A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0590212B	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C1000412A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0990412A	13-Dec
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0930812C	13-Dec



RECALL RESPONSE FORM

Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10/500mg

VOLUNTARY RECALL – RETAIL LEVEL

PRODUCT DESCRIPTION	NDC NUMBER	LOT #	EXP DATE	Units Returning
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C1110412B	13-Dec	
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C1530512A	13-Dec	
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C1151012B	13-Dec	
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C1160712B	13-Dec	
HYDROCODONE APAP 10/500 C3 90 count	0603-3888-02	C0950812B	13-Dec	
HYDROCODONE APAP 10/500 C3 180 count	0603-3888-04	C1110412C	13-Dec	
HYDROCODONE APAP 10/500 C3 180 count	0603-3888-04	C0950812A	13-Dec	
HYDROCODONE APAP 10/500 C3 30 count	0603-3888-16	C1160712C	13-Dec	
HYDROCODONE APAP 10/500 C3 60 count	0603-3888-20	C1160712A	13-Dec	
HYDROCODONE APAP 10/500 C3 60 count	0603-3888-20	C1110412A	13-Dec	
HYDROCODONE APAP 10/500 C3 60 count	0603-3888-20	C0930812A	13-Dec	
HYDROCODONE APAP 10/500 C3 60 count	0603-3888-20	C1141012B	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0740312A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0890812A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0560212A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0780112C	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0790112C	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0910812A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0550212A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0870812A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0880812A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1121012A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1560512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0730112B	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0760112A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1540512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1131012A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0950412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1030412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0720312A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1510512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0740112B	13-Dec	

PRODUCT DESCRIPTION	NDC NUMBER	LOT #	EXP DATE	Units Returning
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0900812A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0730312A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0970412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0750112A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0980412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0770112C	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1050412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1570512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1450512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1111012A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0540212A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1140412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0710312A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1460512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1440512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1130412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0960412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1060412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1550512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1040412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1070412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1071012A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1470512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1061012A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1520512A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1081012A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1101012A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1120412A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0920812A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0860812A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1141012A	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1530512B	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C1160712D	13-Dec	
HYDROCODONE APAP 10/500 C3 100 count	0603-3888-21	C0950812D	13-Dec	
HYDROCODONE APAP 10/500 C3 120 count	0603-3888-22	C0680312A	13-Dec	
HYDROCODONE APAP 10/500 C3 120 count	0603-3888-22	C0670312A	13-Dec	
HYDROCODONE APAP 10/500 C3 120 count	0603-3888-22	C0930812B	13-Dec	
HYDROCODONE APAP 10/500 C3 120 count	0603-3888-22	C0950812C	13-Dec	
HYDROCODONE APAP 10/500 C3 150 count	0603-3888-26	C1160712E	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1500512A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1180712A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1080412A	13-Dec	



PRODUCT DESCRIPTION	NDC NUMBER	LOT #	EXP DATE	Units Returning
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1020412B	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0700312A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0960812A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1010412B	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0690312A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1480512A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0940812A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0720112B	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1090412A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1490512A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1170712A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0630212B	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0640212B	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C1100412A	13-Dec	
HYDROCODONE APAP 10/500 C3 500 count	0603-3888-28	C0941112A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0750312A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0570212B	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0760312A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0970812A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0580212B	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0610212A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0600212A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0620212A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0590212B	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C1000412A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0990412A	13-Dec	
HYDROCODONE APAP 10/500 C3 1000 count	0603-3888-32	C0930812C	13-Dec	

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Store Name _____ DEA # _____
**DEA # is required, if not provided the processing of your form will be delayed.*

Address _____

City _____ State _____ Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____



I have notified my customers that were sold/shipped affected recalled product

Circle one: YES or NO- I did not sell/ship affected product.

I have checked my stock and:

_____ Do not have any stock of the recalled products listed above.

OR

Have quarantined and listed in the box above the quantity to be returned. I will be returning the product to CLS MedTurn, as soon as possible. Upon receipt of this Response Form, CLS MedTurn will issue return authorization labels _____ (please indicate the # of box labels needed.)

If you did not purchase the product directly from the Manufacturer please complete the below section.

Purchased From: Name _____ DEA # _____

Address _____

City _____ State _____ Zip _____

If you have any questions regarding this form or product return please contact
CLS MedTurn, at 1-800-967-5952

Please fax this form to: 1-817-868-5362 or E-mail at: recallnotice@inmar.com



RECALL NOTIFICATION

HYDROCODONE BITARTRATE and ACETAMINOPHEN TABLETS, USP 10 mg/500 mg DUE TO THE POTENTIAL FOR OVERSIZED TABLETS VOLUNTARY NATIONWIDE RECALL OF 101 LOTS

HUNTSVILLE, Ala., **December 6, 2012** - Qualitest, a subsidiary of Endo Health Solutions, (Nasdaq: ENDP) today issued a voluntary nationwide retail level recall for 101 lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg. This includes product with the following NDC numbers and lots beginning with the letter "C".

NDC Number	Bottle Count
0603-3888-16	30
0603-3888-20	60
0603-3888-02	90
0603-3888-21	100
0603-3888-22	120
0603-3888-26	150
0603-3888-04	180
0603-3888-28	500
0603-3888-32	1000

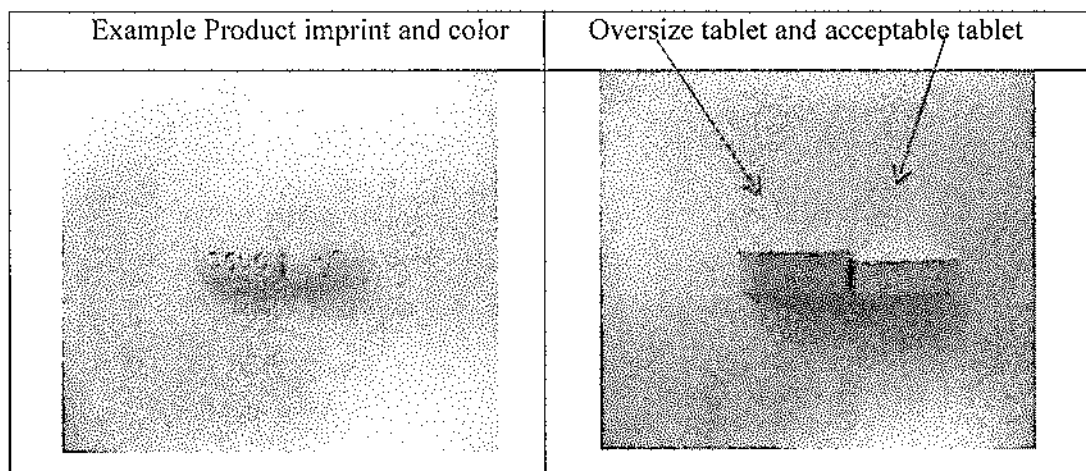
It is possible that a number of tablets from the affected lots may exceed the weight requirement and contain increased levels of hydrocodone bitartrate and acetaminophen than those specified. Hydrocodone bitartrate and acetaminophen 10 mg/500 mg tablets are indicated for the relief of moderate to moderately severe pain.

Unintentional administration of tablets with increased acetaminophen content could result in liver toxicity, especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day. The product label warns consumers that acetaminophen overdose can potentially cause severe liver damage, at times resulting in liver transplant or death. It is very important that consumers do not exceed the maximum daily dose in the prescribing information for this product (no more than 6 tablets per day) and are fully aware of any other prescription or over-the-counter medications they may be taking that contain acetaminophen. If there is any doubt, a consumer should consult with their health care professional.

Taking a higher dose of hydrocodone than intended could result in an increase in the severity or frequency of side effects, such as sedation or respiratory depression, particularly in patients who are elderly, have severe kidney or liver impairment, or are also taking interacting medications, for example other sedating medications or certain antidepressants.

No injuries have been reported to date.

The affected lots, were distributed between February 20, 2012 and November 19, 2012 to wholesale distributors and retail pharmacies nationwide. The lot number can be found on the side of the manufacturer's bottle. Hydrocodone bitartrate and acetaminophen tablets are approximately 16.51 mm in length, pink, capsule-shaped tablets, with "3600" debossed on one side of the tablet and "V" on the other.



Consumers who have the affected lots should contact Qualitest at 1-800-444-4011. Consumers who are unsure if they have the affected lot number or have any concerns about their product should consult their health care professional.

Pharmacists and wholesalers are asked to check their inventories for the affected lots, segregate any material from the lot, and to contact MedTurn at 1-800-967-5952 for instructions on product return. Pharmacies that received the affected lots will receive a copy of this press release with their recall notification information. In order to make your patients aware of this recall, please post this press release prominently in the pharmacy area. The purpose of this posting is to provide the consumer with increased knowledge of the situation,

For more information please contact Qualitest at 1-800-444-4011; Monday through Friday between the hours of 8AM and 5PM CST. Reports of adverse reactions or quality problems can

also be reported to Qualitest at 1-800-444-4011; Monday through Friday between the hours of 8AM and 5PM CST.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either on line, by regular mail, or by fax.

- **Online:**www.fda.gov/medwatch/report.htm
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

This voluntary recall is being made with the knowledge of the U.S. Food and Drug Administration.

About Qualitest

Founded in 1983, Qualitest provides affordable, high-quality generic pharmaceuticals. Featuring a current portfolio exceeding 600 products, the company has grown significantly since its inception and is now ranked in the top ten among all suppliers of generics, based on total prescriptions filled. Qualitest is a wholly owned subsidiary of Endo Health Solutions (Nasdaq: ENDP), a U.S.-based, specialty healthcare solutions company, focused on high-value branded products and specialty generics (www.endo.com).

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