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March 7, 2006

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BY FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Lord, Bissell & Brook LLP ("LBB"), on behalf of its undisclosed client, submits this petition under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to request that the Food and Drug Administration ("FDA") take appropriate remedial action relating to an apparent safety issue regarding Bellatal ER manufactured by Anabolic, Inc. for Qualitest Pharmaceutical, Inc. ("Qualitest"). LBB urges FDA to examine Bellatal ER because independent tests demonstrate it fails to meet United States Pharmacopoeia ("USP") requirements for dissolution and therefore may pose a potential safety issue to consumers. Such a product that fails USP standards for dissolution raises consumer safety issues, is misbranded, and FDA should consider removal of the product from the market. In addition, LBB believes, upon information and belief, that Qualitest's Bellatal ER product may not have been properly approved for marketing by FDA and requests review regarding the approval, if any, of this product. For the following reasons, LBB urges FDA to ensure that the representations made to the public about Bellatal ER are accurate and complete.

A. Actions Requested

Independently conducted tests indicate that Bellatal ER fails USP dissolution testing and, because it dissolves too slowly, raises potential safety issues. Also, because the product releases too slowly, Bellatal ER is misbranded regarding the dosing regimen for the product. In response to the safety issues raised by the failed USP dissolution testing performed by an independent laboratory and the misbranding of this product, LBB requests that FDA consider initiating recalls of Qualitest's Bellatal ER products so that these issues can be addressed and corrected. Because there is also doubt, upon information and belief, that Bellatal ER has been properly approved by FDA, LBB also requests FDA consider reviewing all regulatory submissions relating to Bellatal ER.

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B. Statement of Grounds

1. *Bellatal ER*

Bellatal ER is currently manufactured by Anabolic, Inc. and marketed by Qualitest. Qualitest began marketing Bellatal ER in 2004. Bellatal ER is purportedly used for treating irritable bowel syndrome. Bellatal ER's labeling represents it to be an extended release formulation combining belladonna alkaloid and phenobarbital in tablet form, and containing the following ingredients:

Phenobarbital, USP (3/4 gr.)	48.6 mg
Hyoscyamine Sulfate, USP	0.3111 mg
Atropine Sulfate, USP	0.0582 mg
Scopolamine Hydrobromide, USP	0.0195 mg

Labeling for Bellatal ER claims that the product can be dosed one tablet every twelve hours, which would make the product an extended release formulation.

2. *Safety concerns involving and misbranding of Bellatal ER*

Pursuant to the FFDCA, an applicant must demonstrate that its drug product is safe for human use. 21 U.S.C. § 355(b)(1). Dissolution testing of the Bellatal ER Tablets (Batch 310936A) by a qualified independent laboratory (Covance) using the procedures and acceptance criteria outlined in USP <711> and USP <724> Extended-Release Articles-General Drug Release Standard indicates the tablets fail to meet the USP requirements. The Report of Analysis (attached) indicates the mean percent released of 6 vessels is 49.7% versus the USP requirement of not less than Q(75%) + 5%. Because Covance's testing confirms that Bellatal ER fails USP's minimum requirements for dissolution, it should not properly be branded as a USP or extended release product and should not be dosed, as suggested in the labeling, once every twelve hours.

Not only does the product fail USP's dissolution test, but it is apparent from the test results that there may be a safety concern with this drug. Covance's dissolution test results provided indicate that in twelve hours, less than 50% of the product is released. Based on this data, a consumer taking the product as recommended, once every twelve hours, would receive an insufficient dose of the drug. In other words, someone taking the drug would be getting only half a dose, which means that sufferers of irritable bowel syndrome would not experience any relief from taking this product. Because Bellatal ER provides an insufficient "half-dose," based on the Covance test results, patients suffering from this painful affliction may experience no relief, or may discontinue treatment and continue to suffer needlessly. This safety concerns must be evaluated by FDA in order to protect patients.

Moreover, under FFDCA, a drug is deemed misbranded if its labeling is false or misleading in any particular manner. 21 U.S.C. § 352(a). Since the dosing regimen listed in the labeling is incorrect, as seen above, Bellatal ER is misbranded. As demonstrated by the data provided herein, the product provides an insufficient dose as it is labeled. In addition, to the extent Bellatal ER purports to be USP compliant, and has in fact failed USP's standards for dissolution for an extended release product, it is also misbranded.

For these reasons, FDA should consider initiating a recall of Bellatal ER until such time as the safety to consumers is addressed and the misbranding of Bellatal ER is corrected.

LBB currently does not have any information as to why the Qualitest Bellatal ER product fails USP dissolution or why the product is misbranded.

3. *Questions involving the approval of Bellatal ER*

The agency has, through rule making procedures, accorded new drug status to certain drugs. Included among these are extended release dosage form drugs. Specifically, Title 21 of the Code of Federal Regulations section 310.502(a)(14) provides:

> (a) The drugs listed in this paragraph have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the act. An approved new drug application under section 505 of the act and part 314 of this chapter is required for marketing the following drugs:
>
> . . . .
>
> (14) Timed release dosage forms.

This regulation codifies the new drug status of new extended release drug products such as Bellatal ER tablets. Upon information and belief, Qualitest first launched Bellatal ER tablets in 2004 and may not have followed the procedures for approval of a new drug under 21 U.S.C. § 355(b) or the procedures for approval of an abbreviated application under 21 U.S.C. § 355(j). Because, upon information and belief, Qualitest may not have followed the procedures for obtaining approval of its Bellatal ER product, and because such procedures were required prior to the 2004 launch of the product, on information and belief Bellatal ER is a non-approved product. Until such time as Qualitest has complied with federal law for approval of its Bellatal ER product, Bellatal ER should be removed from the market.

4. *FDA should consider initiating recalls of Bellatal ER*

The Federal Food, Drug and Cosmetic Act requires that products be safe for human use (21 U.S.C. § 355(b)(1)), and that the labeling of a product accurately and completely describe the product and not be false or misleading in any way (21 U.S.C. § 352(a)). Because independently performed USP dissolution tests confirm that Qualitest's Bellatal ER product does not dissolve such that it may be administered once every twelve hours, but in fact dissolves much more slowly, the product may not be considered safe for human use. In addition, Qualitest has mislabeled its product as a USP, extended-release product that can be appropriately dosed every twelve hours. Based on the dissolution data provided, it is doubtful that any representations that Bellatal ER is USP compliant or is appropriately dosed once every 12 hours are accurate. *See* 21 C.F.R. § 201.5(c); 201.56(b). In fact the dissolution data provided strongly suggests that those representations are false and/or misleading.

FDA should consider initiating recalls so that the inaccurate labeling of the Qualitest Bellatal ER product can be removed and corrected. A recall will ensure that the misbranded product no longer is misidentified as being a USP extended-release product that is appropriately dosed every twelve hours.

In addition, Bellatal ER should be recalled until such time as FDA has established that the product has been properly approved for marketing in the U.S. Extended release formulations are considered new drugs, pursuant to FDA rule-making procedures. 21 C.F.R. § 310.502(a)(14). Because, upon information and belief, Qualitest may not have followed the procedures for approval of a new drug, 21 U.S.C. § 355(b), Bellatal ER is not an approved product and should be recalled immediately.

C. Environmental Impact

The petition requests that FDA review the dissolution profile of and representations relating to Bellatal ER. Because the requested action would lead to the institution of a recall, the petition is subject to a categorical exclusion from the requirement of an environmental impact assessment. *See* 21 C.F.R. § 25.30(c).

D. Economic Impact

Information on the economic impact of this petition will be submitted if requested by the Commissioner.

E. Certification

LBB certifies that, to the best of its knowledge, information and belief, this petition includes all information and views on which the petition relies and that it includes representative data and information known to LBB which are unfavorable to the petition.

Respectfully submitted,

LORD, BISSELL & BROOK LLP

David G. Greene

DGG:pm

cc: Thomas W. Abrams, RPh, MBA, Division Director, Drug Marketing, Advertising, and Communication
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Mfg. by:
ANABOLIC, INC.
IRVINE, CA 92614
Rev. 11/03 R0

Mfg. by:
QUALITEST PHARMACEUTICALS, INC.
HUNTSVILLE, AL 35811

Qualitest®

Rx only
100 TABLETS

NDC 0603-2419-21

BELLATAL ER
TABLETS

EXTENDED RELEASE TABLET CONTAINS:

USUAL DOSAGE: One tablet every 12 hours. See package insert.
DISPENSE in a well-closed, light-resistant container as defined in the USP using a child-resistant closure.
STORE at 20°- 25° C (68°- 77° F) [see USP Controlled Room Temperature].

COVANCE
THE DEVELOPMENT SERVICES COMPANY

Covance Laboratories Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704-2523

Tel: 608/241-4471
Fax: 608/241-7227

REPORT OF ANALYSIS

Sample Identification

Product Name:	Bellatal ER Tablets
Batch No.:	310936A
Type of Testing:	Dissolution
Date Issued:	13 Feb 06
Covance Study No.:	7670-030
Covance Sample No.:	MP-51677

Issued To
David Greene
Lord, Bissell & Brook LLP
885 Third Ave, 26th Fl.
New York, NY 10022

Timepoint (hour)	Vessel 1 (% released)	Vessel 2 (% released)	Vessel 3 (% released)	Vessel 4 (% released)	Vessel 5 (% released)	Vessel 6 (% released)	Mean (% released)
2	14.4	14.6	14.7	17.6	17.1	15.3	15.6
4	24.5	22.8	22.6	25.5	26.3	22.6	24.1
6	31.8	30.7	29.9	33.0	33.9	30.3	31.6
8	39.2	37.3	36.6	39.9	40.3	37.0	38.4
12	50.9	48.3	47.7	52.5	51.1	47.8	49.7

Method Reference
USP <724>, Method A (modified)

The USP <724> acceptance criteria are no value exceeds 10% dissolved after the acid stage and each unit is not less than Q (75%) + 5%.

Reviewed by:

Brooke Kasprzak — 13 Feb 06
Representative — Date
Quality Control
Pharmaceutical Analysis

Approved by:

Paul Kirkegaard — 13 Feb 06
Paul Kirkegaard — Date
Principal Investigator
Pharmaceutical Analysis