

# HOGAN & HARTSON L.L.P.

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June 4, 2004

**BY FACSIMILE**

Ms. Gloria Ortega  
Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

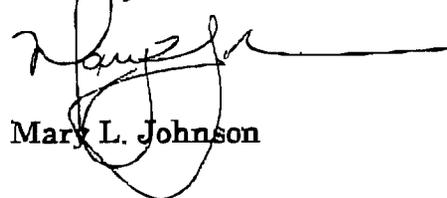
**Re: Exhibit to GSK Comment Filed on Citizen Petition of  
Bell, Boyd, and Lloyd; FDA Docket 2004P-0206/CP1**

Dear Ms. Ortega:

On May 27, 2004, GlaxoSmithKline (GSK) submitted a copy of a petition (FDA Docket No. 2004P-0239) as a comment to the above-referenced Bell, Boyd, and Lloyd (BBL) petition (*see attached coverletter*). Exhibit 6 of the GSK submission is marked confidential, but GSK has already authorized release of the exhibit to the public. Attached is a copy of GSK's authorization letter, which should be applied to Exhibit 6 of the comment GSK filed to the BBL petition.

Thank you for your attention to this matter. Please contact me if you have any questions.

Sincerely,



Mary L. Johnson

Enclosures

cc: C. Elaine Jones and William M. Zoffer, GlaxoSmithKline

2004P-0206

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May 25, 2004

GlaxoSmithKline  
PO Box 13398  
Five Moore Drive  
Research Triangle Park  
North Carolina 27709-3398  
Tel. 919 483 2100  
www.gsk.com

**BY HAND DELIVERY**

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Comment on Citizen Petition of Bell, Boyd, and Lloyd;  
FDA Docket No. 2004P-0206/CP1

Dear Sir or Madam:

The undersigned, on behalf of GlaxoSmithKline (GSK), submits a copy of the enclosed petition (FDA Docket No. 2004P-0239) as a comment to the above referenced citizen petition of Bell, Boyd & Lloyd, LLC (BBL). The BBL petition requests that FDA immediately begin to apply FDA's *Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action* (Apr. 2003) to generic versions of Flonase® (fluticasone propionate). GSK opposes BBL's position for the reasons described in the enclosed petition and supporting documents.

C. Elaine Jones, Ph.D.  
Vice President, US Regulatory Affairs

William M. Zoffer  
Vice President, Assistant General Counsel

cc: David M. Fox  
Mary L. Johnson  
Hogan & Hartson L.L.P.



June 2, 2004

Attn Ms Gloria Ortega  
Division of Dockets Management  
5630 Fishers Lane, Room 1061  
Food and Drug Administration  
Division of Dockets Management  
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Maryland, MD 20852

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**Re: NAS 0; Not Product Specific, General Correspondence; Other  
Re. Attachment 6 to Citizen Petition 2004P-0239 to Issue a Final and Complete  
Guidance Document to Determine Bioequivalence (BE) for Nasal Spray Products  
and  
FDA Docket No. 99D-1738: Comments on Draft Guidance for Industry on  
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for  
Local Action**

Dear Ms Ortega:

We are writing in response to your request for a written release regarding information marked "Confidential" in Exhibit 6 of the above-referenced petition submitted by GlaxoSmithKline on May 19, 2004. Please note that Exhibit 6 is a document that Glaxo Wellcome filed to the public docket on September 9, 1999 (FDA Docket No. 99D-1738: Comments on Draft Guidance for Industry on Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action). A copy of the document is already available to the public on FDA's website at <http://www.fda.gov/ohrms/dockets/dockets/99d1738/c000005.pdf>.

An erroneous document header was included on the Public Docket submission indicating that the documents were confidential. This letter confirms that the previous submissions to Public Docket Number 99D-1738 on September 9, 1999, and June 26, 2003, by Glaxo Wellcome and GlaxoSmithKline respectively, were not confidential, thus you are hereby authorized to release the documents in their current form as part of the Citizen Petition and the Public Docket.

Please let me know if you have any additional questions or concerns.

Sincerely,

Alison Bowers  
Director, Policy, Intelligence, Education, Regulatory Affairs

Copy: C. Elaine Jones, William M Zoffer, GlaxoSmithKline  
David M Fox, Mary L Johnson, Hogan & Hartson LLP

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**IMPORTANT NOTICE**  
**TELECOPY/FACSIMILE COVER LETTER**

**TO:** Gloria Ortega  
Division of Dockets Management  
Food and Drug Administration

**DATE:** 6/4/2004

**FROM:** Mary L. Johnson

**TIME:** 10:19 AM

**TOTAL NO. OF PAGES, INCLUDING COVER:** 4

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**MESSAGE:**

**FOR INTERNAL PURPOSES ONLY**

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**CLIENT NUMBER:** 59524-0035  
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**CONFIRMATION NUMBER:** 301-827-6881