DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-314

Oridion BreathID Inc.
ATTN: Daniel Katzman, VP Business Development
21 Highland Circle
Needham, MA 02494-3038

Dear Mr. Katzman:

Please refer to your new drug application (NDA) dated February 2, 2001, received February 2, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for IDkit:Hp™ containing ^{13}C-Urea (^{13}C-urea tablet for oral solution) 75 mg, and Citrica (citric acid powder for oral solution) 4.0 g for the Oridion BreathID® Breath Test System.

We acknowledge receipt of your submissions dated:

July 5, 2000	November 20, 2001	May 7, 2002	November 21, 2002
July 31, 2000	December 4, 2001	May 27, 2002	November 27, 2002
September 7, 2000	December 6, 2001	September 3, 2002	December 4, 2002
November 28, 2000	December 16, 2001	September 18, 2002	December 15, 2002 (2)
January 30, 2001 (2)	January 3, 2002	October 1, 2002 (3)	December 17, 2002
September 3, 2001	January 6, 2002	November 3, 2002	
October 21, 2001	February 4, 2002 (2)	November 14, 2002	
October 26, 2001	February 28, 2002	November 17, 2002	

The June 26, 2002, submission constituted a complete response to our November 30, 2001, action letter.

This new drug application provides for the use of IDkit:Hp™ containing ^{13}C-Urea (^{13}C-urea tablet for oral solution) 75 mg, and Citrica (citric acid powder for oral solution) 4.0 g for the Oridion BreathID® Breath Test System for use as an aid for initial diagnosis and post-treatment monitoring of *H. pylori* infection.

We have completed our review of this application, as amended and found that it is safe and effective for use as an aid for initial diagnosis and post-treatment monitoring of *H. pylori* infection. Therefore, it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted December 15, 2002, carton, and container labels submitted on December 17, 2002). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten

of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-314**." Approval of this submission by FDA is not required before the labeling is used.

The text in italics below addresses the application of FDA's Pediatric Rule at 21 CFR 314.55 to this NDA. The Pediatric Rule has been challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. The government has not yet decided whether to seek a stay of the court's order. In addition, the government has not yet decided whether to appeal the decision; an appeal must be filed within 60 days. **Therefore, this letter contains a description of the pediatric studies that would be required under the Pediatric Rule, if the Pediatric Rule remained in effect and/or were upheld on appeal.** Please be aware that whether or not these pediatric studies will be required will depend upon the resolution of the litigation. FDA will notify you as soon as possible as to whether this application will be subject to the requirements of the Pediatric Rule as described below. In any event, we hope you will decide to conduct these pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Based on information submitted, we conclude the following:

For use as an aid for initial diagnosis and post-treatment monitoring of H. pylori infection,

- *We are waiving the pediatric study requirement for this application for patients 0-2 years of age.*
- *We are deferring submission of pediatric studies for patients >2-16 years of age until December 31, 2007.*

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request". FDA generally does not consider studies submitted to a NDA before issuance of a Written Request as responsive to the Written Request. Applicants should obtain a Written Request before submitting pediatric studies to an NDA.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susan Peacock, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure (labeling)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Renata Albrecht
12/17/02 04:45:55 PM
NDA 21-314