

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

205383Orig1s000

Trade Name: ORALTAG for oral solution

Generic Name: iohexol

Sponsor: **Interpharma Praha, a.s.**

Approval Date: March 26, 2015

Indications: For use in opacification of the gastrointestinal tract during computed tomography (CT) of the abdomen and pelvis.

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APPROVAL LETTER



NDA 205383

NDA APPROVAL

Interpharma Praha, a.s.
Attention: Ms. Marjory Kadash
Otsuka Pharmaceutical Development & Commercialization
508 Carnegie Center Dr.
Princeton, NJ 08540

Dear Ms. Kadash:

Please refer to the New Drug Application (NDA) 205383, dated and received on March 11, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Oraltag™ (iohexol) for oral solution.

We acknowledge receipt of your amendments dated September 26 and 30, December 17, 2014 and February 25, March 23, 25, and 26, 2015.

The submission dated September 26, 2014, constituted a complete response to our action letter of January 8, 2014.

This new drug application provides for the use of Oraltag™ in computed tomography of the abdomen and pelvis to opacify bowel loops and delineate between normal loops and adjacent organs or areas of suspected pathology. Oraltag™ is not indicated for diagnostic examination of the gastrointestinal tract.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed bottle, foil pouch, and carton labels dated March 26, 2015, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the *Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 205383: Oraltag™**”. Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

Information and Instructions for completing the form can be found at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see: <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

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

SUBMISSION REQUIREMENTS

Submissions to the U.S. FDA CDER – Division of Medical Imaging Products, may be submitted with a cover letter, Forms FDA 1571, 1572, 3674, or 356h (as appropriate) in *triplicate* hard copies along with an electronic copy on CD-Rom (PDF), as follows:

Courier/Overnight/Postal Service

Libero (Lou) Marzella, M.D., Ph.D., Division Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Attention: FDA Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Solely eCTD-formatted electronic submissions to the FDA via Gateway / Global Submit Review (GSR) – See the following links for information:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/default.htm>

Note: Submit all amended / revised protocol, consent form, or other revised document as an annotated version (with red-lined, track-changes) along with a clean revised version and a summary of changes.

If you have any questions regarding this NDA, contact Ms. Thuy M. Nguyen, M.P.H., Senior Regulatory Health Project Manager at: Thuy.Nguyen@fda.hhs.gov or (301) 796-1427.

Sincerely,

{See appended electronic signature page}

Libero Marzella, M.D., Ph.D.
Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Enclosures:

Content of Labeling
Carton and Container Labels

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

/s/

THUY M NGUYEN
03/26/2015

LIBERO L MARZELLA
03/26/2015