



U.S. Food and Drug Administration
Protecting and Promoting Public Health

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Considerations for PET ANDAs

Office of Generic Drugs

April 14, 2010

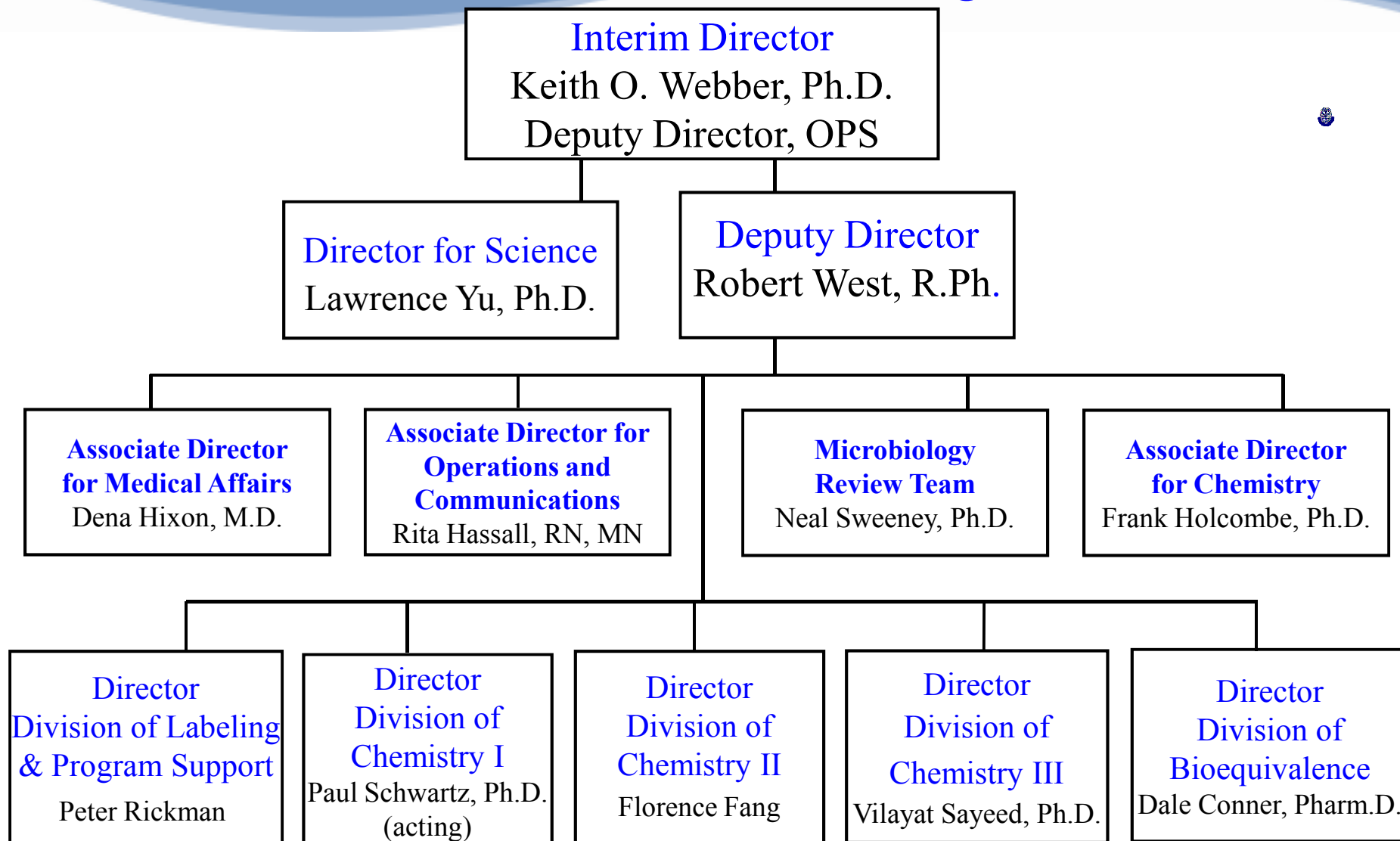


Agenda

- Office of Generic Drugs: background information
- RLDs and Suitability Petitions
- Submission requirements for an ANDA
- Approval process and ANDA Formatting
- Resources



Office of Generic Drugs





OGD Facts

- OGD receives approximately 800 ANDAs each year.
- There are currently NO user fees assessed for the review of ANDAs.
- All CMC reviews for PET products are coordinated by Chemistry Team 1 within Chemistry Division 1.
- CMC reviews for PET original ANDAs are consulted to the Office of New Drug Quality Assessment(ONDQA), Branch V of the Division of Pre-marketing Assessment. OGD completes BE, Micro and Labeling reviews.
- There are currently no approved ANDAs listed in the Orange Book for FDG or Ammonia N 13.



Key Point -

To submit an ANDA, there must be a reference listed drug (RLD).



Current RLD for Ammonia N 13

Active Section of Orange Book

-NDA 22119 Ammonia N 13 30-300 mCi/mL Feinstein

Discontinued Section of Orange Book

-Not applicable



Ammonia N 13

Appl No	Prod No	ExclusivityCode	ExclusivityExpiration
<u>N022119</u>	001	<u>NCE</u>	Aug 23, 2012
<u>N022119</u>	001	<u>W</u>	Aug 23, 2012

NCE NEW CHEMICAL ENTITY

**W EXCLUSIVITY ON THIS APPLICATION
EXPIRING ON THIS DATE HAS BEEN
WAIVED BY SPONSOR - SEE SECTION
1.8 OF ORANGE BOOK PREFACE
WAIVED EXCLUSIVITY**



Current RLDs for FDG in the Active and Discontinued sections of the OB

Active section of Orange Book

-NDA 21870 Fludeoxyglucose F-18 20-200 mCi/mL Feinstein

-NDA 21768 Fludeoxyglucose F-18 10-100 mCi/mL Weill Medical

Discontinued section of Orange Book

-NDA 20306 Fludeoxyglucose F-18 4-40 mCi/mL Downstate Clinical

-NDA 20306 Fludeoxyglucose F-18 4-90 mCi/mL Downstate Clinical

******The Agency has already made a formal determination that the two different strengths of NDA 20306 were not discontinued for reasons of Safety and/or Efficacy. Therefore, these products may be cited as the RLD for an ANDA.**



Advice -

Carefully select your RLD. Once your ANDA is filed you MAY NOT amend your ANDA to reference a different RLD.



Suitability Petitions

- Differences in Strength when compared to the RLD:
 - May still be eligible for submission as an ANDA
 - 21 CFR 314.93, 10.20 and 10.30
 - SP must be approved before you may submit your ANDA
 - SP process is public
 - SP 97P-0432/CP1 has previously been approved for FDG



What are the requirements for a generic drug?

- Same active ingredient(s)
- Same route of administration
- Same dosage form
- Same strength
- Same conditions of use

Compared to reference listed drug (RLD) - (brand name product)



Specific Requirements for Drug Products intended for Parenteral Use submitted as ANDAs

- 314.94(a)(9)(iii)
 - Equivalence of inactive ingredients
 - Exception excipients
- Waiver requests
 - Request for waiver of the requirement to conduct in-vivo BE studies under 320.22(b)
 - (Applicant) requests that the FDA waive the requirement for the submission of evidence demonstrating in vivo bioequivalence for (proposed drug product). The (proposed drug product) meets the provisions of 21 CFR 320.22(b)(1)(i) and (ii).



Patent Certifications

- All ANDAs must submit a patent certification per 21 CFR 314.94(a)(12)
 - PI through PIV
 - No relevant patents statement
 - In the opinion and to the best knowledge of insert applicant name, there are no patents that claim the listed drug referred to in this application or that claims a use of the listed drug.
 - Exclusivity statements are required even if the NDA cited as the Reference Listed Drug is not protected by exclusivity. Example for NDA not protected by exclusivity:
 - According to the publication, Approved Drug Products with Therapeutic Equivalence Evaluations(Orange Book) (insert the reference listed drug) is not entitled to a period of marketing exclusivity under Section 505(j)(4)(D) of the act.



GDEA Certifications and Statements

Generic Drug Enforcement Act of 1992

- **Debarment Certification:**

- (Name of Applicant) certifies that (the applicant) did not and will not use in any capacity the services of any person debarred under section 306 of the act in connection with this application

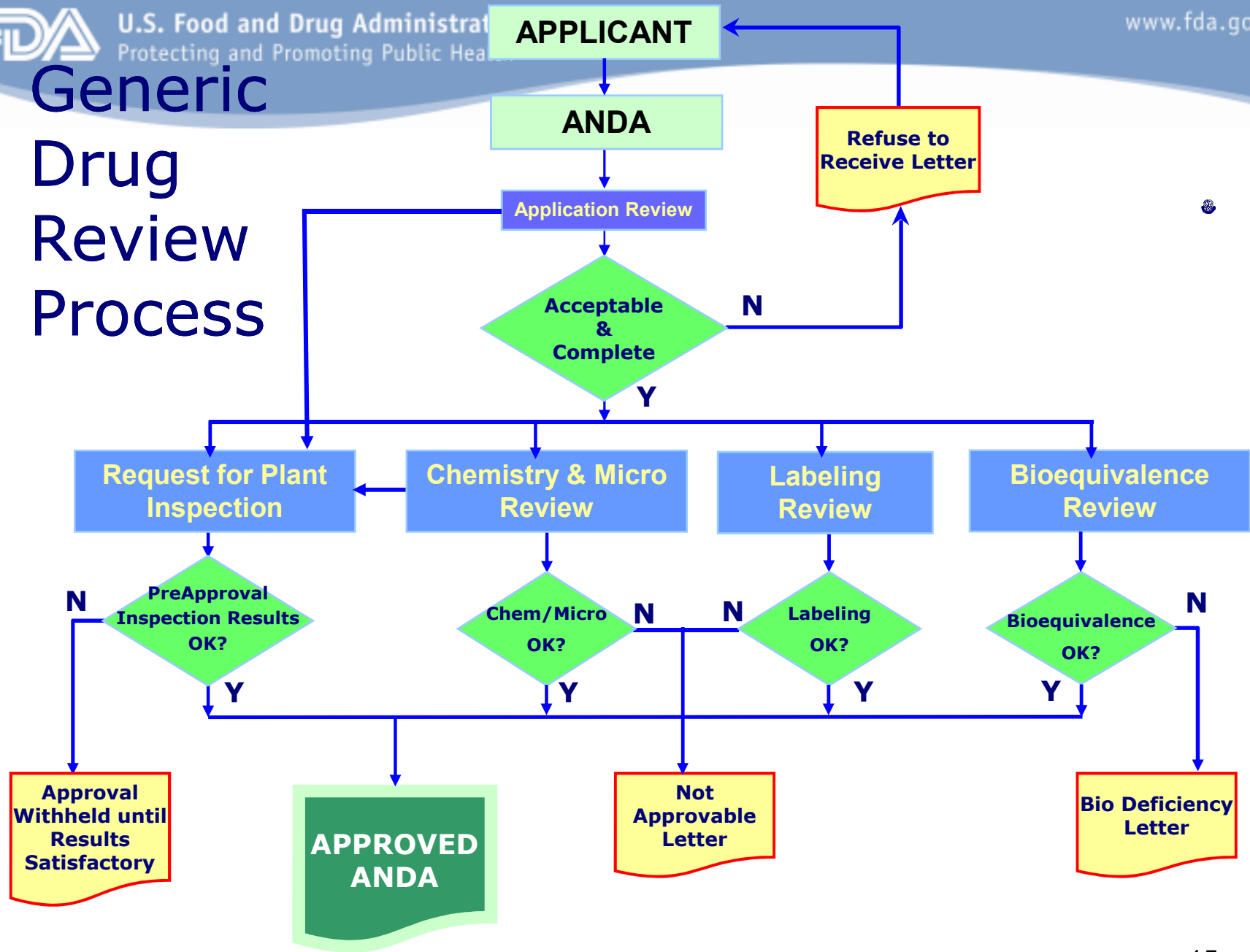
- **Convictions Statement:**

- If the firm nor it's affiliated persons have convictions to list then the applicant may state that neither the applicant nor its affiliated persons responsible for the development or submission of the application has been convicted of a relevant offence within the last five years.

- Alternatively the applicant must list the names of all individuals convicted within the last 5 years as described in section 306(a) and (b)



Generic Drug Review Process





ANDA Format

- Common Technical Document or CTD
 - Module 1: Administrative or Regional
 - Forms, Certifications, Labeling, BE waiver request, etc.
 - Module 2: Summaries
 - Quality Overall Summary, Drug Substance and Drug Product Information, Clinical BE Summary
 - Module 3: Quality-CMC information
 - Broken down into Drug Substance(3.2.S), Drug Product(3.2.P) and Regional(3.2.R) subsections
 - Module 4: not applicable to ANDA submissions
 - Module 5: Clinical Study Reports
 - PET ANDAs will need to submit section 5.3.1 which is related to formulation
- OGD's ANDA Checklist-contains detailed information regarding where documents are to be placed.



ANDA Format con't

- Electronic submissions in CTD(eCTD) format are preferred:
 - Ease of review, facilitates consult process, is the primary standard for all electronic submissions after January 1, 2008.
 - May be submitted via the ESG(Gateway) or on physical media(CD or DVD)
- Hard copy or paper submissions are acceptable.
- Submissions in Traditional format are discouraged.



Recommendations

- Use the ANDA filing checklist as a template for compiling your ANDA.
- Have the Office of Generic Drugs review your proposed formulation prior to submission of your ANDA.
 - Controlled Correspondence
- Contact either myself or Dat Doan (Project Manager for PET drug products) with questions regarding the submission and/or approval process.



Where to Submit

- Addresses
 - Currently
 - Office of Generic Drugs/CDER/FDA
Attn: Keith O. Webber, Ph.D
Metro Park North II
7500 Standish Place
Rockville, MD 20855
 - Later this year (after August 2010-date subject to change)
 - FDA/Office of Generic Drugs/CDER/FDA
Attn: Keith O. Webber, Ph.D
Metro Park North VI
7620 Standish Place
Rockville, MD 20855

***Check OGD website for address update



Submission Resources

- eCTD website:
<http://www.fda.gov/cder/regulatory/ersr/ectd.htm>
- eCTD Table of Contents:
<http://www.fda.gov/cder/regulatory/ersr/5640CTOC-v1.2.pdf>
- OGD Filing Checklist
http://www.fda.gov/cder/ogd/anda_checklist.pdf
- OGD website
<http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm119100.htm>

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Resources for You

- [Drugs@FDA](#)
- [Inactive Ingredient Search for Approved Drug Products](#)
- [Abbreviated New Drug Application \(ANDA\): Generics](#)
- [Orange Book Query](#)
- [Generic Drugs: Information for Industry](#)
- [Understanding Generic Drugs](#)

Office of Generic Drugs

Welcome from the Director, Office of Generic Drugs

Note: We highly recommend that firms consider submitting documents in electronic format. The OGD document room has limited space and resources to maintain paper documents.


Organization and Contact Information


- [Office of Generic Drugs: Chemistry and Bioequivalence Review Teams](#)
- [Office of Generic Drugs: Phone Directory](#)

Contact Us

Office of Generic Drugs

 240-276-9310

 240-276-9327 Fax

 genericdrugs@fda.hhs.gov

Immediate Office

7500 Standish Place

Rockville, MD 20855



Contact information

- Martin H. Shimer: Branch Chief, Regulatory Support Branch, FDA, Office of Generic Drugs
– martin.shimerii@fda.hhs.gov
- Dat Doan: Project Manager, Division of Chemistry 1, Team 1, FDA, Office of Generic Drugs
– dat.doan@fda.hhs.gov
- Identify in the subject line that the e-mail is related to a PET drug product.
- Phone numbers are on the OGD webpage and subject to change.