DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)

REPORT ON RESEARCH USE OF RADIOACTIVE DRUGS

STUDY SUMMARY

Form Approved: OMB No. 0910-0053. Expiration Date: 2/29/08

DATE OF SUBMISSION

FOR FDA USE ONLY

Public reporting burden for this collection of information is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to address on the right.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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

A. GENERAL INFORMATION

1. TYPE OF REPORT *(please mark one)* :

☐ Special Summary

☐ Annual Report *(Use a separate copy of this Form FDA 2915, to summarize each study conducted during the reporting period and attach to Form FDA 2914.)*

2. RDRC COMMITTEE NUMBER

3. NAME OF INSTITUTION

4. NAME AND ADDRESS OF IRB

B. SPECIFIC INFORMATION

1. RESEARCH PROJECT

a. Title of Research Project

b. Study ID Number	c. Original Study Approval Date	d. Study Termination Date

2. BRIEF DESCRIPTION OF THE PURPOSE OF THE RESEARCH PROJECT

3. NAME OF RESPONSIBLE INVESTIGATOR *(NOTE: Also name the prescribing physician if other than the responsible investigator.)*

B. SPECIFIC INFORMATION *(Continued)*

4. PHARMACOLOGICAL DOSE (Based on pharmacological data available from studies in *human* subjects, the dose should be known not to cause any clinically detectable pharmacological effect in human beings.)

Study Drug #1

Provide the Reference, supplied by the investigator and/or used by the RDRC, to show that the amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings, based on pharmacological dose calculations on data available from published literature or from other valid human studies [21 CFR 361.1 (b)(2) and (d)(2)].

(a) Name of the **nonradioactive** drug

(b) Mass dose

(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose	(b.2) No-observed-effect-level (NOEL) mass dose

c. Number of doses per subject.		(d) Route of administration (i.e., I.V., P.O., etc.)	(e) If the radio active drug or nonradioactive drug is under an IND, list IND Number.
(c.1) Maximum number of doses per subject per year	(c.2) Maximum number of doses per subject per protocol		

Study Drug #2

Provide the Reference, supplied by the investigator and/or used by the RDRC, to show that the amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings, based on pharmacological dose calculations on data available from published literature or from other valid human studies [21 CFR 361.1 (b)(2) and (d)(2)].

(a) Name of the **nonradioactive** drug

(b) Mass dose

(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose	(b.2) No-observed-effect-level (NOEL) mass dose

c. Number of doses per subject.		(d) Route of administration (i.e., I.V., P.O., etc.)	(e) If the radio active drug or nonradioactive drug is under an IND, list IND Number.
(c.1) Maximum number of doses per subject per year	(c.2) Maximum number of doses per subject per protocol		

Study Drug #3

Provide the Reference, supplied by the investigator and/or used by the RDRC, to show that the amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings, based on pharmacological dose calculations on data available from published literature or from other valid human studies [21 CFR 361.1 (b)(2) and (d)(2)].

(a) Name of the **nonradioactive** drug

(b) Mass dose

(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose	(b.2) No-observed-effect-level (NOEL) mass dose

c. Number of doses per subject.		

(c.1) Maximum number of doses per subject per year	(c.2) Maximum number of doses per subject per protocol	(d) Route of administration (i.e., I.V., P.O., etc.)	(e) If the radio active drug or nonradioactive drug is under an IND, list IND Number.

B. SPECIFIC INFORMATION *(Continued)*

4. PHARMACOLOGICAL DOSE *(Continued)*

Study Drug #4

Provide the Reference, supplied by the investigator and/or used by the RDRC, to show that the amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings, based on pharmacological dose calculations on data available from published literature or from other valid human studies [21 CFR 361.1 (b)(2) and (d)(2)].

(a) Name of the **nonradioactive** drug

(b) Mass dose

(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose	(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose

c. Number of doses per subject.		(d) Route of administration (i.e., I.V., P.O., etc.)	(e) If the radio active drug or nonradioactive drug is under an IND, list IND Number.
(c.1) Maximum number of doses per subject per year	(c.2) Maximum number of doses per subject per protocol		

Study Drug #5

Provide the Reference, supplied by the investigator and/or used by the RDRC, to show that the amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings, based on pharmacological dose calculations on data available from published literature or from other valid human studies [21 CFR 361.1 (b)(2) and (d)(2)].

(a) Name of the **nonradioactive** drug

(b) Mass dose

(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose	(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose

c. Number of doses per subject.		(d) Route of administration (i.e., I.V., P.O., etc.)	(e) If the radio active drug or nonradioactive drug is under an IND, list IND Number.
(c.1) Maximum number of doses per subject per year	(c.2) Maximum number of doses per subject per protocol		

Study Drug #6

Provide the Reference, supplied by the investigator and/or used by the RDRC, to show that the amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings, based on pharmacological dose calculations on data available from published literature or from other valid human studies [21 CFR 361.1 (b)(2) and (d)(2)].

(a) Name of the **nonradioactive** drug

(b) Mass dose

(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose	(b.1) Maximum mass dose (i.e.µ, g or mg) of ***nonradioactive*** drug administered per subject, per single dose

c. Number of doses per subject.		(d) Route of administration (i.e., I.V., P.O., etc.)	(e) If the radio active drug or nonradioactive drug is under an IND, list IND Number.
(c.1) Maximum number of doses per subject per year	(c.2) Maximum number of doses per subject per protocol		

B. SPECIFIC INFORMATION *(Continued)*

5. LIST THE RADIONUCLIDE(S) WITH THE ASSOCIATED STUDY DRUG FROM ITEM 4 AND IDENTIFY AND QUANTITATE THE MAXIMUM RADIONUCLIDIC CONTAMINANTS IN THE ADMINISTERED RADIOACTIVE STUDY DRUG(S).

	Radionuclide Label	Associated Study Drug	Radionuclidic Contaminant	Percent (%)
#1				
#2				
#3				
#4				
#5				
#6				

6. RADIATION ABSORBED DOSE -- List reference, (e.g., ICRP) and/or show calculations used to estimate the radiation absorbed dose for each radioactive study drug used in this project.

#1	
#2	
#3	
#4	
#5	
#6	

Show calculations here *(may continue calculations on attachment if necessary).*

B. SPECIFIC INFORMATION *(Continued)*

6. RADIATION ABSORBED DOSE *(Continued)*

FOR A SPECIAL SUMMARY: Enter information below for a representative subject, using the provided format (refer to "Specific Instructions" pages for more information).

a.		b.	c.	d.
AGE	SEX	ACTIVITY OF RADIOACTIVE STUDY DRUG(S) ADMINISTERED AND OTHER ASSOCIATED PROCEDURES	ABSORBED DOSE PER SINGLE ADMINISTRATION *(for each radioactive study drug)*	TOTAL DOSE PER ORGAN / PER YEAR
		Radioactive Drug Amount _____ MBq *or* _____ µCi *or* _____ mCi of _____ *radioactive study drug* *Other Associated Procedures* ☐ PET transmission scans ☐ CT ☐ DEXA ☐ X-Ray ☐ Other *(Specify:)* _____	*From Radioactive Drug* _____ mSv (Rem) / whole body _____ mSv (Rem) / lens of eye _____ mSv (Rem) / gonads _____ mSv (Rem) / _____ (critical organ) _____ mSv (Rem) / _____ (Blood forming organ) *From Other Associated Procedures* _____ mSv (Rem) / whole body _____ mSv (Rem) / lens of eye _____ mSv (Rem) / gonads _____ mSv (Rem) / _____ (critical organ) _____ mSv (Rem) / _____ (Blood forming organ)	_____ mSv (Rem) / whole body _____ mSv (Rem) / lens of eye _____ mSv (Rem) / gonads _____ mSv (Rem) / _____ (critical organ) _____ mSv (Rem) / _____ (Blood forming organ) *Additional comments or information, if any, regarding Total Dose:*

FOR AN ANNUAL REPORT: Enter information below for each subject studied, using the provided format (refer to "Specific Instructions" pages for more information).

B. SPECIFIC INFORMATION *(Continued)*

6. RADIATION ABSORBED DOSE *(Continued)*

a.		b.	c.	d.
AGE	SEX	ACTIVITY OF RADIOACTIVE STUDY DRUG(S) ADMINISTERED AND OTHER ASSOCIATED PROCEDURES	ABSORBED DOSE PER SINGLE ADMINISTRATION *(for each radioactive study drug)*	TOTAL DOSE PER ORGAN / PER YEAR

B. SPECIFIC INFORMATION *(Continued)*

6. RADIATION ABSORBED DOSE *(Continued)*

a.		b.	c.	d.
AGE	SEX	ACTIVITY OF RADIOACTIVE STUDY DRUG(S) ADMINISTERED AND OTHER ASSOCIATED PROCEDURES	ABSORBED DOSE PER SINGLE ADMINISTRATION *(for each radioactive study drug)*	TOTAL DOSE PER ORGAN / PER YEAR

e. NUMBER OF RESEARCH SUBJECTS STUDIED THIS REPORTING YEAR	
f. NUMBER OF RESEARCH SUBJECTS STUDIED THIS REPORTING YEAR UNDER 18 YEARS OF AGE	
g. CUMULATIVE NUMBER OF RESEARCH SUBJECTS STUDIED FROM INITIATION OF THIS PROTOCOL THROUGH END OF THIS REPORT	
h. TOTAL NUMBER OF RESEARCH SUBJECTS FOR WHICH THIS PROTOCOL IS APPROVED	

If additional space is needed, attach separate sheets.

7. CLAIM OF CONFIDENTIALITY

Contents of this report are available for public disclosure unless confidentiality is requested by the investigator and it is adequately shown by the investigator that the report constitutes a trade secret or confidential commercial information as defined in 21 CFR 20.61.

☐ I do not claim confidentiality.
☐ I claim confidentiality; justification is attached.

RETURN COMPLETED FORM TO:

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

Attention: RDRC

8. **CERTIFICATION**

The undersigned certify that the study outlined above complies with Title 21 CFR Section 361.1 and that the responses are true and accurate as outlined above.

SIGNATURE OF INVESTIGATOR	DATE
SIGNATURE OF CHAIRPERSON OF RADIOACTIVE DRUG RESEARCH COMMITTEE	DATE

Instructions for Completing Radioactive Drug Research Committee (RDRC) Report on Research Use of Radioactive Drugs -- Study Summary (Form FDA 2915)

Basic research with radioactive drugs may be conducted without an Investigational New Drug Application (IND) when the research is conducted under a FDA-approved Radioactive Drug Research Committee (RDRC) and other conditions, as specified in the RDRC regulations, are met.

RDRC regulations are contained in Title 21, Code of Federal Regulations, Part 361.1 (21 CFR 361.1) and maybe accessed at the following web address:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=361.1

Guidance regarding RDRC procedures is available from the FDA Center for Drug Evaluation and Research, Office of Oncology Drug Products, 5901-B Ammendale Road, Beltsville, MD 20705-1266. Information about the FDA RDRC program is available at the RDRC web site at the following web address:
http://www.fda.gov/cder/regulatory/RDRC/default.htm

Access to RDRC reporting Forms (2914 - Membership Summary and 2915 - Study Summary) in both Adobe Acrobat and Microsoft Word versions, which can be filled out and saved on your computer, can be obtained through the RDRC web site or from the following FDA Forms website:
http://www.fda.gov/opacom/morechoices/fdaforms/default.html

The following instructions address only the administrative aspects of preparing and submitting Form FDA 2915 (Study Summary) for the following RDRC submissions:

1. **Annual Report** (requirement – 21 CFR 361.1 (c)(3) Reports)
   The annual report, due on or before January 31 of each year, consists of submission of Form FDA 2914 (Membership Summary) and Form FDA 2915 (Study Summary) for each study conducted during the preceding calendar year. A Form FDA 2915 (Study Summary) should be submitted even for studies that did not enroll any subjects in the preceding calendar year but have been previously approved by the RDRC and are still open and ongoing.

2. **Special Summary** (requirement – 21 CFR 361.1 (c)(3) Reports)
   A special summary must be submitted to FDA at the time the RDRC approves research studies involving more than 30 subjects or involving subjects under the age of 18. A special summary consists of the submission of Form FDA 2915 (Study Summary) and a justification for the number of subjects or the inclusion of subjects under 18 years of age. In addition, provide the maximum radiation dose commitment for the organs listed in 21CFR361.1(b)(3)(i) for a representative subject.

WHERE TO SEND THE SUBMISSION: Food and Drug Administration
Center for Drug Evaluation and Research
Office of Oncology Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

ATTN: RDRC

Specific instructions for filling out this report begin on the next page.

SPECIFIC INSTRUCTIONS FOR FILLING OUT FORM FDA 2915

(Titles and numbers, when used, correspond to the item blocks on Form FDA 2915)

When completing this form, and not enough space is provided for reporting in a section, attach a separate sheet with each information reporting section appropriately identified.

Section A. General Information

1. **Type of Report** – Check the appropriate box indicating whether this is a special summary or an annual report. If this is a special summary, provide a justification for the need to study more than 30 subjects or to study subjects under the age of 18. Studies involving minors must be supported with review by a qualified pediatric consultant to the RDRC and documented in the special summary.
2. **RDRC Committee Number** – Provide the committee number assigned by FDA when the RDRC was initially approved.
3. **Name of Institution** – Provide the name of the medical institution to which the RDRC is affiliated.
4. **Name and Address of IRB** – Provide the name and address of the Institutional Review Board (IRB) that approved the study protocol.

Section B. Specific Information

1. **Research Project** – Check the appropriate box indicating whether this is a special summary or an annual report. If this is a special summary, provide a justification for the need to study more than 30 subjects or to study subjects under the age of 18. Studies involving minors must be supported with review by a qualified pediatric consultant to the RDRC and documented in the special summary.
   a. *Title of Research Project* – Provide a unique and brief title of the research protocol that includes the name of the radioactive drug[1].
   b. *Study ID Number* – Provide the unique number assigned to the research protocol by the Institution or RDRC for tracking purposes. A study ID number ***must*** be provided.
   c. *Original Study Approval Date* – Provide the date the research protocol was approved by the RDRC for the first time.
   d. *Study Termination Date* – Provide the date the research protocol was completed or terminated.
2. **Concise and Complete Description of the Research Project** – Self-explanatory.
3. **Name of Responsible Investigator –** Provide the name of the Principal Investigator and the name of the prescribing physician, if other than the Principal Investigator.
4. **Pharmacological Dose** – This is the mass dose of the nonradioactive drug to be investigated that will not cause a clinically detectable pharmacologic effect in humans. Please cite relevant published literature or other valid human studies supporting the use of this dose. If necessary, attach a separate sheet.
   a. *Name of the Nonradioactive Drug* – Provide the name of the nonradioactive drug being investigated. The use of the term "drug" in this section is synonymous with the terms moiety, active ingredient, compound, or ligand.
   b. *Mass Dose*
      b.1. *Maximum mass dose* – This is the maximum amount of nonradioactive drug administered per subject per single dose at the expiration time of the radiolabeled drug to be administered. Indicate amount in terms of mass or weight expressed in units of µg or mg only.
      b.2. *No observed effect level (NOEL) mass dose* – This is the pharmacologic dose of the nonradioactive drug that will not cause a clinically detectable pharmacologic effect in humans. This is not necessarily the administered dose.
   c. *Maximum number of doses per subject* – Specify the number of administrations of the radioactive drug a research subject may receive per year and the total number of doses specified in the protocol.
      c.1 -- *Maximum number of doses per subject per year*
      c.2 -- *Maximum number of doses per subject per protocol*
   d. *Route of administration* – Indicate the route of administration (e.g. I.V., P.O., etc.).
   e. *If the drug is under an IND, list IND Number* – If the radioactive drug or the nonradioactive drug is being investigated under an Investigational New Drug Application (IND), identify the IND number.
5. **List the radionuclides with the associated drug and identify and quantitate the maximum radionuclide contaminants in the administered radioactive drug upon expiration.** – Self-explanatory.

[1.] The term "radioactive drug" is defined in 21 CFR 310.3(n) and includes a "radioactive biological product" as defined in 21 CFR 600.3(ee).

Section B. Specific Information *(Continued)*

6. **Radiation Absorbed Dose**

- All study summaries should list the specific reference(s) that were used to estimate the dose commitments (e.g., ICRP Publication 80 Table 3.2.1). For those radioactive drugs for which no reference(s) are available, list your assumptions and show your calculations. The report should include the dose contribution from the administered radioactive study drug and any other associated procedures (i.e., would not have occurred but for the study) contributing to the radiation absorbed dose.

- For a **special summary**, provide the maximum radiation dose commitment to the whole body, the critical organ, and each organ as specified in 21 CFR 361.1(b)(3)(i) received by a *representative* subject.

- For an **annual report**, provide the radiation dose commitment to the whole body, the critical organ, and each organ as specified in 21 CFR361.1(b)(3)(i) received by *each* subject receiving the radioactive study drug during the reporting calendar year. For each subject, provide (a) Age and Sex; (b) the amount of radioactivity administered for each radioactive study drug used; (c) the absorbed dose to the whole body, the critical organ, and each organ specified in 21 CFR 361.1(b)(3)(i) per single administration for each radioactive study drug and other procedures associated with the study; and (d) the resultant cumulative radiation dose to the subject for the whole body and organs referenced above within the calendar year.

a. *Age and Sex* – Specify the age and sex for each individual research subject studied.

b. *Activity of Radioactive Study Drug(s) Administered and Other Associated Procedures* – For each individual research subject identified in column a, provide the amount of radioactivity administered along with the name of each radioactive study drug received. Express each amount of radioactivity in MBq, µCi, or mCi. FDA prefers you use the International System of Units (SI). Note: 37 MBq =1mCi.

For other associated procedures (i.e., would not have occurred but for the study), identify the sources of radiation.

c. *Absorbed Dose per Single Administration* – Provide theradiation absorbed dose in mSv [1mSv = 100 mrem] for each target organ, e.g. whole body, lens of eye, gonads, and critical organ(s).

d. *Total Dose Per Organ/Per Year* – Provide the total cumulative radiation dose from the radioactive study drug(s) and associated procedures received per organ for a 12-month period of time, usually a calendar year, unless otherwise specified.

e. *Number of Research Subjects Studied this Reporting Year* – Self-explanatory.

f. *Number of Research Subjects Studied this Reporting Year Under 18 years of Age* – Self-explanatory.

g. *Cumulative Number of Research Subjects Studied from Initiation of this Protocol Through End of this Report* – Self-explanatory.

h. *Total Number of Research Subjects for Which this Protocol is Approved* – Self-explanatory.

7. **Claim of Confidentiality** – Indicate whether or not you are claiming confidentiality. If confidentiality is claimed, attach a justification demonstrating that this report constitutes a trade secret or confidential information as defined in 21 CFR 20.61.

8. **Certification** – The Principal Investigator and the RDRC chairperson must sign the form. Indicate the date(s) the form is signed by the Principal Investigator and by the RDRC chairperson.