DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC) REPORT ON RESEARCH USE OF RADIOACTIVE DRUG STUDY SUMMARY

Form Approved: OMB No. 0910-0053.
Expiration Date: 10/31/04

NOTE: 21 CFR 361.1 Requires submission of summaries of research studies annually and upon approval of studies which involve more than 30 subjects or any subject under 18 years of age. Approval of a committee may be withdrawn at any time for failure of the committee to comply.

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:

Food and Drug Administration
Center for Drugs Evaluation and Research
CDE - III (HFD - 160)
5600 Fishers Lane
Rockville, MD 20857

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.

TYPE OF REPORT *(PLEASE CHECK 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)*

RDRC COMMITTEE NUMBER	NAME OF INSTITUTION

1. TITLE OF RESEARCH PROJECT

2. CONCISE AND COMPLETE DESCRIPTION OF THE PURPOSE OF THE RESEARCH PROJECT

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

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

a. Name of the ***nonradioactive*** moiety.

b. Maximum amount *(i.e., mg)* of ***nonradioactive*** moiety administered per subject, per single dose and/or the *minimum* specific activity (i.e. mCi/mg) of drug at the time of administration.

c. Maximum number of doses per subject.	d. Route of administration *(i.e., I.V., P.O., etc.)*	e. If nonradioactive moiety *(drug)* is under an IND, list IND Number.

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5. LIST THE RADIONUCLIDE(S) AND IDENTIFY AND QUANTITATE THE MAXIMUM RADIONUCLIDIC CONTAMINANTS IN THE ADMINISTERED RADIOACTIVE RESEARCH DRUG(S).

Radionuclide	Radionuclidic Contaminant	Percent (%)

6. RADIATION ABSORBED DOSE

a. If this is a *special study summary*, provide the maximum radiation dose commitment to the whole body, the critical organ, and each organ specified in 21 CFR 361.1(b)(3)(i) received by a *representative* subject. Write, also, a justification for the need to study more than 30 subjects or 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.

b. If this is a study summary submitted within the annual report, provide the radiation dose commitment to the whole body, the critical organ, and each organ specified in 21 CFR 361.1(b)(3)(i) received by *each* subject receiving the radioactive research drug during the reporting calendar year. For each subject, provide: (a) Age and Sex; (b) the amount of radioactivity administered (*i.e., uCi)* for each radioactive drug used in the study and any other procedures used in conjunction with the study; (c) the absorbed dose (*mR)* 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 drug or 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.

All study summaries should list the references that were used to estimate the dose commitments. The report should include the dose contribution from the administered radioactive research drug and any other procedures related to the study (*i.e., would not have occurred but for the study)* contributing to the radiation absorbed dose. **NOTE: FIRST ENTRY BELOW SHOULD LIST AN EXAMPLE OF A REPRESENTATIVE DOSE TO A REPRESENTATIVE SUBJECT.** Other entries will indicate sex, age, and amount of radioactivity administered per dose, per subject.

LIST REFERENCE AND/OR ATTACH CALCULATIONS USED TO ESTIMATE THE RADIATION ABSORBED DOSE.

a.		b.	c.	d.
SEX	AGE	ACTIVITY & RADIONUCLIDE/ ADMINISTRATION	ABSORBED DOSE PER SINGLE ADMINISTRATION	TOTAL DOSE PER ORGAN / PER YEAR
		____ uCi _____ (radionuclide)	_____ mR / whole body _____ mR / lens of eye _____ mR / gonads _____ mR / _____ (critical organ) _____ mR / _____ (blood forming organ)	_____ mR / whole body _____ mR / lens of eye _____ mR / gonads _____ mR / _____ (critical organ) _____ mR / _____ (blood forming organ)

6. RADIATION ABSORBED DOSE - *Continued*

a.		b.	c.	d.
SEX	AGE	ACTIVITY & RADIONUCLIDE/ ADMINISTRATION	ABSORBED DOSE PER SINGLE ADMINISTRATION	TOTAL DOSE PER ORGAN, PER YEAR

6. RADIATION ABSORBED DOSE - *Continued*

a.		b.	c.	d.
SEX	AGE	ACTIVITY & RADIONUCLIDE/ ADMINISTRATION	ABSORBED DOSE PER SINGLE ADMINISTRATION	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 sheets of plain bond

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 Drugs Evaluation and Research
CDE - III (HFD - 160)
5600 Fishers Lane
Rockville, MD 20857

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