Form Approved; OMB No. 0910-0338.
Expiration Date: August 31, 2005
See OMB statement on reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

TRANSMITTAL OF LABELS AND CIRCULARS

1. LABEL REVIEW NO. AND REVISION

2. CHECK ONE ☐ Draft ☐ Final *(in distribution)*

NOTE: *No license may be granted unless this completed submittal form has been received (U.S. Public Health Service Act, Section 351; the Federal Food, Drug, and Cosmetic Act, Section 502; and Title 21 U.S. Code of Federal Regulations, Part 600).*

3. **MANUFACTURER NAME AND RETURN ADDRESS**		4. LICENSE NO. 5. REGISTRATION NO.
6. **PRODUCT NAME**		

7. **LABELING DETAILS**

LABEL TYPE CODE *(see below)* | *REPLACES PREVIOUS LABEL* REVIEW & REVISION NO.

LABEL TYPE CODES
(select only one)

CIRC	Circular	**DILT**	Diluent	**PCKR**	Packer
CONT	Container	**BLST**	Blister	**SHIP**	Shipping
PACK	Package	**CRTN**	Carton	**BULK**	Bulk
				OTHR	Other *(Specify in Comments)*

8. SUBMISSION REASONS *(Check all that apply)*

- ☐ New Product
- ☐ New Scientific Information
- ☐ New Indication
- ☐ Editorial, Format
- ☐ Dosage Change
- ☐ Contraindications, Adverse Reactions, Precautions
- ☐ Manufacturing Method Change
- ☐ New Formulation
- ☐ Anticoagulant/ Additive Change
- ☐ Other *(Specify in Comments)*

9. CHECK THE BOX(es) INDICATING FORMAT OF THIS SUBMISSION *(More than one may be checked.)* ☐ Paper ☐ Electronic

10. CHECK BOX IF THIS LABELING IS IN SUPPORT OF: ☐ Application ☐ Supplement ☐ Part of an Annual Report

Associated BLA/ PLA No. Report

11. COMMENTS *(Include any Manuf. ID number, description or revision no. of label being replaced. IF FINAL PRINTED, provide LOT NO. & DATE of FIRST USE.)*

12. **AUTHORIZED OFFICIAL**	SIGNATURE	DATE

THE SPACES BELOW ARE FOR USE BY CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

COMMENTS *(See attached comments* ☐)

REVIEWED BY	SIGNATURE	DATE
RETURNED BY	SIGNATURE	DATE

GENERAL INSTRUCTIONS FOR COMPLETING FORM FDA 2567

Type or print legibly in ink. Submit **three** copies of preliminary proofs and drafts. **For revised labeling, indicate where changes have been made on the labeling copy.** Assemble and staple each set, including attachments. **Submit each type of labeling (carton, container, insert, etc.) with a Form FDA 2567.** The transmittal form should be dated and signed by the authorized official. Send to the Food and Drug Administration, Center for Biologics Evaluation and Research (CBER), HFM-99, 1401 Rockville Pike, Rockville, Maryland 20852-1448. **Either Form FDA 2567 or Form FDA 2253 may be used for submissions of advertising and promotional labeling.** Send to the above address and reference the mail code HFM-602.

INSTRUCTIONS FOR COMPLETING NUMBERED ITEMS ON FORM FDA 2567

1. If this is the initial submission for a new or revised label, leave blank and FDA will assign a number. If this is a resubmission of pending labeling, you may include the previously assigned number.

2. Check the draft box if this is a revised draft or a final draft label. Check the final box if item is final printed labeling that has been distributed.

3. Enter the manufacturer's name and complete address where the review comments should be returned.

4. If establishment is licensed, enter license number.

5. Enter the registration number that will appear on the label for blood and blood components for submissions that are directed to the Office of Blood Research and Review. This field should be left blank for other product submissions.

6. Enter the proper name (e.g. established or United States Adopted Name) followed by the trade name, if any, for the product.

7. For **LABEL TYPE COD**E, select only **ONE** label type and enter into the box. Multiple labels may be submitted under each Form 2567 although all must be of the same type and product. Each label type requires an additional form. For **REVIEW AND REVISION NO**., if Form 2567 applies to an initial submission or revised labeling submitted under 21 CFR 601.12, complete the **REPLACES PREVIOUS LABEL** box with the most recent marketed labeling of this type and the date it was returned by CBER. If form applies to a resubmission of pending labeling and the FDA has already assigned this number, complete the box with revision number indicated on the copy of the Form 2567 that FDA returned to company, and the date FDA signed the **REVIEWED BY** date box. The **REPLACES PREVIOUS LABEL** boxes do not apply to labeling for brand new products.

8. Check the box that best applies to your current submission. The **Anticoagulant/Additive Change** applies only to submissions directed to the Office of Blood Research and Review.

9. Check the applicable box(es). If any part of the labeling is on diskette, CD, or other electronic media, the electronic box should be checked.

10. Check one of the boxes if this labeling is **associated with or** in support of an original application, supplement, or annual report and enter the reference or submission tracking number in the **Associated BLA/PLA No.** box.

11. Complete with any comments that are important for the review, including manufacturer ID number(s), description or revision numbers of labels being replaced, submission reason not covered in checklist in item number 8, label type code not included in item number 7, etc. If this is FINAL LABELING that has been distributed, provide the lot number and the date of distribution in this space.

12. An authorized official signs his/her name in this space followed by the date that the labeling is being submitted to CBER.
