

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		1. LABEL REVIEW NO. AND REVISION														
<b>TRANSMITTAL OF LABELS AND CIRCULARS</b>		BN070012														
		2. CHECK ONE <input checked="" type="checkbox"/> Draft <input type="checkbox"/> 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	Presenius Kabi Deutschland GmbH c/o Carolina Research Group, Inc. (US Agent) POB 32295 Raleigh, NC 27622 Phone: (919) 881-9900 Fax: (919) 881-0014		4. LICENSE NO.  5. REGISTRATION NO.													
6. PRODUCT NAME	6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride infusion Voluven®															
7. LABELING DETAILS	LABEL TYPE CODE (see below) <table border="1"><tr><td>CIRC</td><td></td><td></td></tr></table>		CIRC			8. SUBMISSION REASONS (Check all that apply) <table border="0"><tr><td><input checked="" type="checkbox"/> New Product</td><td><input type="checkbox"/> New Scientific Information</td></tr><tr><td><input type="checkbox"/> New Indication</td><td><input type="checkbox"/> Editorial, Format</td></tr><tr><td><input type="checkbox"/> Dosage Change</td><td><input type="checkbox"/> Contraindications, Adverse Reactions, Precautions</td></tr><tr><td><input type="checkbox"/> Manufacturing Method Change</td><td><input type="checkbox"/> New Formulation</td></tr><tr><td><input type="checkbox"/> Anticoagulant/Additive Change</td><td><input checked="" type="checkbox"/> Other (Specify in Comments)</td></tr></table>	<input checked="" type="checkbox"/> New Product	<input type="checkbox"/> New Scientific Information	<input type="checkbox"/> New Indication	<input type="checkbox"/> Editorial, Format	<input type="checkbox"/> Dosage Change	<input type="checkbox"/> Contraindications, Adverse Reactions, Precautions	<input type="checkbox"/> Manufacturing Method Change	<input type="checkbox"/> New Formulation	<input type="checkbox"/> Anticoagulant/Additive Change	<input checked="" type="checkbox"/> Other (Specify in Comments)
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9. CHECK THE BOX(es) INDICATING FORMAT OF THIS SUBMISSION (More than one may be checked.) <input checked="" type="checkbox"/> Paper <input checked="" type="checkbox"/> Electronic																
10. CHECK BOX IF THIS LABELING IS IN SUPPORT OF: <input checked="" type="checkbox"/> Application <input type="checkbox"/> Supplement <input type="checkbox"/> Part of an Annual Report			Associated BLA/ PLA No. BN070012													
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.) Submission of revised draft package insert (vers. December 18, 2007) which incorporates revisions requested by the FDA on December 14, 2007																
12. AUTHORIZED OFFICIAL	SIGNATURE		DATE 12/18/2007													
THE SPACES BELOW ARE FOR USE BY CENTER FOR BIOLOGICS EVALUATION AND RESEARCH																
COMMENTS (See attached comments <input type="checkbox"/> ) See page #1 of approval letter for instructions on submitting FPL																
REVIEWED BY	SIGNATURE	DATE	APPROVED By Lawrence Landow MD at 7:43 am, Dec 21, 2007													
RETURNED BY	SIGNATURE	DATE	REVIEWED By Pauline Cottrell at 4:01 pm, Dec 20, 2007													