Acknowledgment and Consent for Disclosure of Section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 18 U.S.C. §208 Particular Matter Waiver

Name:

Barry Massie, M.D.

Committee:

Cardiovascular and Renal Drugs Advisory Committee

Meeting Date(s):

December 11 & 12, 2007

I acknowledge that contingent upon public disclosure of the following financial interests submitted on my FDA Form 3410 and related to the agenda item: (1) new drug application (NDA) 22-034, vernakalant hydrochloride injection, 20 milligrams per milliliter, for the proposed indication of use for conversion of atrial fibrillation to normal sinus rhythm. Vernakalant Hydrochloride Injection is sponsored by Astellas Pharma, Inc., and co-sponsored with Cardiome Pharma Corp; and, (2) new drug application (NDA) 22-123, Pulzium (tedisamil sesquifumarate)IV solution 2 milligrams per milliliter, for the proposed indication of use for conversion of atrial fibrillation or atrial flutter to normal sinus rhythm. Pulzium (tedismil sesquifumarate) is sponsored by Solvay Pharmaceuticals, Inc., a subsidiary of Solvay S.A. I am eligible to receive a particular matter waiver under Section 712(c)(2)(B) and 18 U.S.C. §208.

Type of Interest	Involvement	Magnitude
Member of Steering Committee on an Unrelated Issue	Competitor	Less than \$10,001 per year

I hereby request that FDA make this information publicly available on my behalf at the start of the advisory committee meeting for which it is issued by reading the statement into the record at the time of the meeting. I understand that without public disclosure of the interests, the waivers are not valid.

Signature Date