

Exhibit A

Protocol for the Manufacture and Distribution of Thyrogen

Genzyme is in the process of transferring its fill/finish manufacturing operations (as provided in the Decree) for Thyrogen from its Allston Facility to other manufacturing sites. Until the transfer is effected, FDA authorizes Genzyme, under Paragraph 5.A of the Decree, to manufacture and distribute Thyrogen at and from the Allston Facility provided that (i) it distributes the drug only to customers (i.e., entities that purchase Thyrogen kits directly from Genzyme in the United States) who execute one copy of the Certificate of Procedures Related to Medical Necessity, and (ii) Genzyme distributes each kit of Thyrogen in the United States with one copy of the Dear Healthcare Provider Letter, which contains FDA's criteria for determining whether Thyrogen is medically necessary for a given patient. The Dear Healthcare Provider Letter and the Certificate of Procedures Related to Medical Necessity are attached to the Decree as Exhibits B and C, respectively.

Genzyme shall not promote the use of Thyrogen by patients in the United States who do not meet the medical necessity criteria as long as fill/finish manufacturing operations for Thyrogen for the United States market continue at the Allston Facility, and failure to abide by this prohibition may result in the imposition of liquidated damages pursuant to Paragraph 22 of the Decree. Shipping Thyrogen to a customer that has executed a Certificate of Procedures Related to Medical Necessity attached as Exhibit C to the Decree shall not constitute promotion, even if physicians prescribe drug from such shipments to patients who do not meet the medical necessity criteria.

1. Procedures for Initiating Fill/Finish Manufacturing Operations for Thyrogen

No later than thirty (30) days prior to a date upon which it intends to conduct fill/finish manufacturing operations for Thyrogen for the U.S. market, Genzyme shall provide written notification to FDA of its intent to conduct such operations ("fill/finish notification"). The fill/finish notification shall be signed by Genzyme's President, Global Manufacturing and shall include, at a minimum, the following information: (1) the current inventory of Thyrogen kits within Genzyme's possession, custody, and control; (2) an estimate for the number of Thyrogen kits needed and the time period in which Genzyme expects to distribute those kits; (3) any other information forming the basis for Genzyme's determination that additional fill/finish manufacturing operations for Thyrogen are necessary to meet demand in the United States; (4) the date(s) of the scheduled fill/finish manufacturing operations; (5) the size of the Thyrogen lot(s) to be produced; and (6) the lot number(s) for the Thyrogen to be produced.

Upon receiving Genzyme's fill/finish notification, and prior to Genzyme's commencement of fill/finish manufacturing operations for Thyrogen, FDA may order Genzyme in writing to (1) revise, modify, expand, or supplement the information contained in the fill/finish notification; (2) suspend or cancel the planned fill/finish manufacturing operations; and/or (3) take any other actions with respect to fill/finish manufacturing operations for Thyrogen that FDA deems appropriate.

2. Recordkeeping and Reporting Requirements for Distribution of Thyrogen

Genzyme shall not distribute Thyrogen manufactured under Paragraph 5.A of the Decree to its customers without first: (a) providing each customer with a copy of the Dear Healthcare Provider Letter regarding Thyrogen, and (b) having the customer execute a single Certificate of Procedures Related to Medical Necessity. Genzyme shall retain in its files copies of the executed Certificate of Procedures Related to Medical Necessity from each customer to which it distributes Thyrogen for so long as the Decree remains in effect. Upon request, Genzyme shall provide copies to FDA of the executed Certificates of Procedures Related to Medical Necessity.

In addition, with each box of Thyrogen drug product destined for the domestic market, Genzyme shall enclose multiple copies of the Dear Healthcare Provider Letter, equal to the number of individual kits of Thyrogen contained in the box. Genzyme shall maintain a record of all orders for, and shipments of, Thyrogen manufactured and distributed under Paragraph 5.A of the Decree, for both domestic and foreign markets, and shall provide such record to FDA upon request.

Each month for the first three months after entry of the Decree, and quarterly thereafter until inventory filled and finished at the Allston Facility for the U.S. market has been depleted, Genzyme shall provide a report to FDA (“distribution report”) containing the following information: (1) the inventory of Thyrogen within Genzyme’s possession, custody, and control; (2) the names, addresses, and telephone numbers of all customers executing a Certificate of Procedures Related to Medical Necessity for Thyrogen and the dates upon which Genzyme received the forms; (3) the number of kits of Thyrogen shipped to each customer in the time period covered by the report (either monthly or quarterly), the lot numbers of those kits, and the dates of those shipments; and (4) if applicable, the total number of kits shipped to each customer in the year prior to entry of the Decree.