§ 252. Procedures for determinations relating to package, or form of dosage or administration, of certain drugs. 1. If the department of health makes an initial determination that a particular package, or form of dosage or administration, of a drug shall be excluded in accordance with the provisions of paragraph (b) of subdivision one of section two hundred forty-one of this title, the executive department shall notify the manufacturer of such drug product that the executive department intends to seek the exclusion of such package, or form of dosage or administration, from the program and shall provide such manufacturer with the reasons therefor together with the facts which the department relies upon to support its initial determination. The manufacturer shall have fifteen days after receiving such exclusion notice to notify the executive department of an intent to appeal the decision. If the manufacturer fails to notify the executive department of an intent to appeal within the time specified in this section, the commissioner of health shall forthwith determine whether the package, or form of dosage or administration, shall be excluded from the program. If the manufacturer notifies the executive department of an intent to appeal, the manufacturer shall submit to the executive department within forty-five days of receiving such exclusion notice, the basis of the manufacturer's appeal. Within fifteen days of receiving such submission from the manufacturer, the executive department shall provide to the manufacturer any additional facts concerning the drug product that the department relies upon to support its initial determination. Within ten days of receiving such facts, the manufacturer may submit additional facts concerning the drug package, or form of dosage or administration. Based on the facts submitted pursuant to this section, the commissioner of health shall make a final determination, in accordance with the standard set forth in paragraph (b) of subdivision one of section two hundred forty-one of this title, as to whether the package, or form of dosage or administration, of the drug product shall constitute a covered drug for the purposes of this article. A determination to exclude the drug package, or form of dosage or administration, shall be subject to judicial review pursuant to article seventy-eight of the civil practice law and rules.

2. The commissioner of health shall establish by regulation an

appropriate process allowing drug packages, or forms of dosage or administration, finally determined under this section not to be covered drugs for the purposes of this title to be dispensed to program participants for whom such drug packages, or forms of dosage or administration, are medically indicated as certified to by a physician treating such participant. Any such drug package, or form of dosage or administration, so certified as medically indicated for a specific participant in accordance with such regulations shall be a covered drug for the purpose of this title.