§ 516.30 Annual reports for a MUMS-designated drug.

Within 14 months after the date on which a MUMS drug is granted designation and annually thereafter until approval, the sponsor of a MUMS-designated drug shall submit a brief progress report on the drug to the investigational new animal drug file addressed to the Director of the Office of Minor Use and Minor Species Animal Drug Development that includes the following information:

(a) A short account of the progress of drug development including a description of studies initiated, ongoing, and completed, and a short summary of the status or results of such studies;

(b) A description of the investigational plan for the coming year, as well as any anticipated difficulties in development, testing, and marketing; and

(c) A brief discussion of any changes that may affect the MUMS-designated drug status of the product. For example, situations in which testing data demonstrate that the proposed intended use is inappropriate due to unexpected issues of safety or effectiveness.

§ 516.31 Scope of MUMS-drug exclusive marketing rights.

(a) After conditional approval or approval of an application for a MUMS-designated drug in the dosage form and for the intended use for which MUMS-