Mr. Jarrod Collier
Center for Devices and Radiological Health
Food and Drug Administration
Attention: FDA-2022-N-0008
10903 New Hampshire Ave.
Bldg. 66, Rm. 5214
Silver Spring, MD 20993-0002
Jarrod.Collier@fda.hhs.gov

Via email

Dear Mr. Collier:

Genentech, a member of the Roche Group, appreciates the opportunity to submit comments regarding the Notice of Meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee on November 10, 2022.[1] Genentech is a leading biotechnology company dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening illnesses.

We understand that the purpose of the upcoming meeting is for the committee to discuss and make recommendations on the classification of ophthalmic dispensers into Class I (general controls). Specifically, based on *Federal Register* notice ("Notice"), we understand that the discussion and potential classification recommendation will be limited to those types of ophthalmic dispensers that FDA considers to be *unclassified pre-amendment* devices. This will include a discussion of the known risks and safety/effectiveness concerns and a general classification recommendation for such ophthalmic dispensers.

Our comments on the subject matter of the Notice focus on the definition and scope of the types of the "ophthalmic dispensers" FDA is considering classifying into Class I. Primarily, we ask that FDA clarify that the term "ophthalmic dispensers" is limited to *lower-risk non-invasive and non-implanted* ophthalmic dispensers and will not encompass implantable drug-delivery ophthalmic devices or prefilled ophthalmic syringes that are intended to penetrate the eye. Products that are intended to be implanted into the eye or to penetrate the eye have different risk considerations from those for lower-risk ophthalmic dispensers not intended to penetrate the eye. Consequently, implantable drug-delivery ophthalmic devices and ophthalmic syringes are likely to require additional regulatory controls to provide a reasonable assurance of safety and effectiveness vis-à-vis ophthalmic dispensers not intended to touch or penetrate the eye.

We understand that certain types of implantable drug-delivery ophthalmic devices and ophthalmic syringes may be outside the scope of the proposed classification discussion in that they fall within existing classifications and thus are not "unclassified." Further, we assume that some such products, although potentially unclassified, would be out of scope in that they are not pre-amendment devices.

In any event, we ask that the agency make clear that it is not proposing for this Class I classification discussion to encompass any ophthalmic dispensers that are intended to be implanted into the eye or to penetrate the eye. This can be achieved by defining the term "ophthalmic dispenser" as categorically excluding any device intended to penetrate the eye or

[1] 87 Fed. Reg. 61091 (Oct. 7, 2022).

be implanted in the eye. Alternatively, the agency could consider defining the types of products subject to the upcoming discussion and potential classification as "Ophthalmic Dispensers for External Use Only" (and further defining this device type as excluding any ophthalmic dispensers intended to be implanted or intended to penetrate the eye).

Although we are not aware of a formal FDA definition of "ophthalmic dispenser" in regulations, we note that 21 C.F.R. 200.50 Subpart C (governing ophthalmic preparations and dispensers) refers generally to "eye cups, eye droppers, and other dispensers intended for ophthalmic use."[2] We believe that based on the historical treatment of ophthalmic dispensers by FDA, the specific listing in the regulation of eye cups and eye droppers as the examples of ophthalmic dispensers, and topical administration being the route of administration for self-administered ophthalmic drugs, that the term "ophthalmic dispensers" should be limited to the types of containers that are used to contain ophthalmic medications for patient self-administration, i.e., eye dropper bottles for liquid products that are low viscosity such that they can be dispensed through an eye dropper using gravity and a tube requiring manual pressure for higher viscosity drugs such as ointments.

We also request that in addition to the committee recommendations on the classification of ophthalmic dispensers, FDA should in response to this committee meeting discussion publish a more precise and complete regulatory definition of the term "ophthalmic dispenser" for purposes of any potential Class I classification rulemaking to make it clear that this term does not include more complex ophthalmic drug delivery devices such as implantable drug-delivery ophthalmic devices and pre-filled syringes that deliver ophthalmic drugs.

We thank you for considering our comments and welcome any follow-up questions.

Sincerely,

Eric Olson,
Vice President, Global Head, Product Development Regulatory Policy
Genentech, a member of the Roche group

[2] We understand that FDA now considers this regulation to be obsolete.