4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5319]

Notice of Followup to Notice of Public Hearing and Request for Comments on Devices Proposed for a New Use With an Approved, Marketed Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a followup on a *Federal Register* document issued on September 26, 2017, that announced a public hearing and requested comments on a potential approach to enable device sponsors to obtain marketing authorization for their products labeled for a new use with an approved, marketed drug when the sponsor for the approved drug does not wish to pursue or collaborate on the new use, referred to in the notice as devices referencing drugs (DRDs). After further consideration and in light of the comments received, FDA does not intend to pursue the potential approach described in the referenced *Federal Register* document at this time.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 32, Rm. 5130, Silver Spring, MD 20993, 301-796-8941, combination@fda.gov.

SUPPLEMENTARY INFORMATION: FDA issued a *Federal Register* document on September 26, 2017 (82 FR 44803), entitled "Devices Proposed for a New Use With an Approved, Marketed Drug; Public Hearing; Request for Comments". The document announced a public hearing and requested comments on a potential approach to enable device sponsors to obtain

marketing authorization for their products labeled for a new use with an approved, marketed drug when the sponsor for the approved drug does not wish to pursue or collaborate on the new use. Such new uses generally involve a change in how the drug is used or administered, such as a change in dose, route, or rate of administration, or use of the approved drug for an indication for which it is not approved. As discussed in the document, such DRDs raise unique public health, scientific, regulatory, and legal issues, which the potential approach was intended to address. However, after further consideration and in light of the comments received during the public hearing and submitted to the docket, FDA does not intend to pursue the potential approach described in the document at this time.

Dated: May 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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