Novavax COVID-19 Vaccine Booster Authorized

The Novavax COVID-19 vaccine, adjuvanted received FDA Emergency Use Authorization for use as a first booster dose. The Novavax booster dose is intended for individuals aged 18 years or older for whom an FDA-authorized messenger RNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate and for individuals aged 18 years or older who would otherwise not receive a COVID-19 vaccine booster. The 0.5-mL booster dose may be administered intramuscularly at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine.

Novavax

The vaccine previously received Emergency Use Authorization for a 2-dose primary series for individuals aged 12 years or older. The two 0.5-mL intramuscular doses are given 3 weeks apart.

Cooling Device to Prevent Chemotherapy Oral Mucositis Gains Authorization

A device that cools the inside of the mouth during chemotherapy cancer treatment, reducing the likelihood and severity of oral mucositis, gained FDA marketing authorization. The device is already licensed for clinical use in the UK and Europe and is scheduled for US market launch shortly, according to the company statement. The company also seeks to license the device to major ultrasound manufacturers for integration with diagnostic products.

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However, the FDA said it continues to believe that devices of this type present potential additional risks compared with native tissue repair, including mesh exposure and erosion, and therefore maintains that they do not have a favorable benefit-risk profile. Premarket applications were rejected for 3 such devices in April 2019.

The current finding is the last in a series of postmarket surveillance studies of surgical mesh for transvaginal repair of pelvic organ prolapse ordered by the FDA that have failed to reach the end point of superiority to native tissue repair that an FDA advisory committee recommended in February 2019. Previously, 36-month postmarket studies of 2 such devices manufactured by Boston Scientific also showed similar efficacy and safety as natural tissue repair, according to the FDA.

The agency’s concerns about mesh for pelvic organ prolapse repair date back to at least 2008, when it issued a safety warning based on more than 1000 reports. Erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and incontinence were most frequently reported. In 2011 the warning was updated to state that such complications were not rare.

This led to the FDA reclassifying mesh for pelvic organ prolapse as a high-risk class III medical device in January 2016, requiring substantial evidence of efficacy and safety for market approval. As a result, all such products were eventually removed from the market. The FDA continues to monitor urogynecological surgical mesh for adverse events including low-frequency but life-altering events that may occur. — Howard D. Larkin

Note: Source references are available through embedded hyperlinks in the article text online.