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Digital medicine Take 2: Proteus Digital Health, Otsuka resubmit FDA application

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It has been about one year since Proteus Digital Health filed a joint application with Otsuka for a medication monitoring tool for patients taking Otsuka's drug Abilify, only to have the FDA send them back to the drawing board with a complete response letter. Now Proteus and Otsuka are taking another crack at approval.

The Class 2 resubmission will be reviewed by both Drug and Device review divisions of the FDA, a spokeswoman said in emailed responses to questions. The drug division takes the lead, since the drug provides the primary therapeutic action. This Digital Medicine would be the first-ever approval of such a drug-device combination product.

For the resubmitted application, the FDA requested more information on "further human factors investigations. The goal of human factors testing is to evaluate use-related risks and confirm that individuals can use the system safely and effectively," a company press release noted. The FDA is expected to take action on the new drug application in the fourth quarter.

Asked what Proteus has learned in the past year regarding the human factors testing, the spokesperson said the human factors validation studies were done to refine the utility of the "digital medicine" to reduce use errors from 12.1 percent to 1.5 percent.

"New designs and approaches were implemented and evaluated, with the intention of reducing the number of "errors" made by an individual using the system, e.g., putting the patch in the wrong place or interpreting the weekly view incorrectly," the spokesperson said.

The target patient populations for the proposed platform include adults with schizophrenia, bipolar I disorder, and major depressive disorder.

The technology behind the ingestible sensor is pretty interesting. It is activated by stomach juices and the sensor sends signals to a skin patch electrode, which wirelessly transmits information such as vital signs, body position and verification of medication ingestion.

Although Proteus' ingestible sensor has been cleared by the FDA and Abilify was approved some time ago, the NDA seeks to pair Proteus' ingestible sensor and companion wearable platform with the drug maker's medication. The goal is to securely measure patient medication-taking patterns, track physiological data and self-reported behavioral information. If Proteus and Otsuka's joint application wins approval, it could usher in many more joint applications with Proteus.

The larger goal is for the Proteus platform to be used to tailor medicines more closely to reflect each of person's medication-taking patterns and lifestyle choices. The complexities behind adherence loom large in the face of attempts to improve it. But given that poor adherence can lead to complications, hospitalization and endanger patients lives in some cases, a green light on the joint NDA could usher in a whole new way of working with patients.

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