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US FDA's New Acting Generics Chief Relearning System After 24 Years Of Experience

by Derrick Gingery

Acting OGD Director Susan Rosencrance says in an interview that the generics assessment system has evolved substantially since she moved to the Office of Pharmaceutical Quality in 2015.

The new acting director of the US Food and Drug Administration's Office of Generic Drugs, Susan Rosencrance, spent 24 years working there, but that experience is largely outdated after only a few years at the Office of Pharmaceutical Quality, a close partner in the ANDA assessment program.

Rosencrance, who had been director of the Office of Lifecycle Drug Products in OPQ, said OGD has changed substantially, thanks to the generic drug user fee program. Her early days running OGD have been spent learning as much as possible about the program "from the inside," such as "the interactions there and how they keep the applications flowing."

"It's amazing how much OGD has evolved and
changed since I've been working in OPQ," she said during a 3 November interview with the *Pink Sheet*. "I'm just focused on learning about all the changes they've made."

Rosencrance became acting OGD director after the 8 October departure of Sally Choe, who has since become head of global clinical development and regulatory affairs at *SK Bioscience*.

Rosencrance said another priority is ensuring GDUFA III is implemented smoothly. She would not discuss whether she was interested in becoming the permanent director.

"I don't want to speculate on the future. I like to focus on the here and now," Rosencrance said. "I'm dedicated to making sure GDUFA III, year one of it, goes successfully, and making sure we

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continue to meet our commitment to the program and continue to serve public health as well as the dynamic industry out there."



Source: FDA

The FDA is conducting a national search for a permanent OGD director. Center for Drug Evaluation and Research Director Patrizia Cavazzoni likely selected Rosencrance as acting director in part because of her extensive experience in the generics program. In addition to working at OGD and OPQ, Rosencrance also was an FDA GDUFA III negotiator. (Also see "*Next US FDA Generics Leader Must Have 'Frank Conversations' With Colleagues, Industry, Former OGD Director Says*" - Pink Sheet, 27 Sep, 2022.)

GDUFA III Will Improve 'Robust' ANDA Assessment Program

Rosencrance expects GDUFA III will continue improving the already solid program.

"I feel like GDUFA III really will help take the program to the next level, but really FDA already has a very robust generic drug program," Rosencrance added. "I see GDUFA III as just building on that success."

GDUFA III, which launched 1 October, is intended to streamline approvals of complex generics, as well as increase the first-cycle approval rate. Sponsors will be able to conduct additional meetings with agency officials (Also see "*GDUFA III: Convening Enhanced Mid-Cycle Meeting Will Cost Sponsors*" - Pink Sheet, 29 Oct, 2021.), and will see some assessment functions adjusted to avoid approval delays. (Also see "*FDA's 'Imminent Action' Policy Likely Not Best Path For ANDAs To Address Late Brand Label Changes*" - Pink Sheet, 26 Jul, 2022.)

Congress approved the program renewal on the last day of the fiscal year, much later than stakeholders preferred. But Rosencrance said that did not cause OGD major problems.

"We were gearing up to make sure on day one of GDUFA III when an application comes in we were able to route it in the right way and be able to handle it as smoothly as possible," she said.

The late renewal did not allow the FDA to collect some of the user fees on its normal schedule, which created some financial stress. The FDA asked sponsors to send prescription drug program fees as soon as possible because reserves could not last for more than a few weeks. (Also see "*US FDA: Please Pay PDUFA Program Fees ASAP*" - Pink Sheet, 10 Oct, 2022.)

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OGD Comfortable With Pandemic Work

Rosencrance also said that she thought OGD is now comfortable with the workload changes caused by the COVID-19 pandemic.

“We developed those systems and have it down to more of a science,” she said. “We know how to deal with these applications when they come in now. I would say we’ve been able to adjust and adapt and handle what comes our way at this point.”

The FDA was one of the federal agencies under the most stress during the pandemic as the primary reviewer and decision-maker for vaccines and treatments. OGD largely helped expedite generic applications that were intended to help alleviate shortages of drugs needed to treat COVID-19 patients. (Also see "*Seven Days In March: NDA-BLA and ANDA Approval Output Diverged As Coronavirus Teleworking Began*" - Pink Sheet, 29 Apr, 2020.)

OGD also continued assessing routine applications and met most of its user fee program goals throughout the pandemic. (Also see "*Generic Drug Approvals Still Winning The Pandemic At US FDA*" - Pink Sheet, 3 Aug, 2020.)

Some groups within the FDA appear ready to move beyond the COVID-19 priorities that have been in place since the pandemic began. Center for Biologics Evaluation and Research Director Peter Marks said recently that he wants staff to return to normal operations in 2023. (Also see "*CBER’s Goal To Reach Normal Ops In 2023 Includes Clearing IND, Meeting Backlogs In 2022*" - Pink Sheet, 11 Jul, 2022.)

The agency also has conducted some hybrid meetings, which was seen as a step toward once again hosting in-person sessions. (Also see "*In-Person US FDA Meetings Returning? Agency Will Support Those Events At HQ*" - Pink Sheet, 3 Oct, 2022.)

But the FDA indicated in a recent advisory that meetings with sponsors will remain virtual. The formal definition of face-to-face meeting was changed in PDUFA VII to include in-person or virtual meetings with audio and visual components engaged. (Also see "*PDUFA VII Communications: Earlier PMR Talks, Formal Meeting Additions*" - Pink Sheet, 24 Aug, 2021.)

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