

Large CRO to Acquire FDA

By Norman M. Goldfarb

Inside sources have revealed that a large CRO is preparing to announce an agreement in principal to acquire the U.S. Food & Drug Administration's Center for Drug Evaluation and Research (CDER). The CRO has not been identified.

The FDA has been struggling recently with criticism from all sides. As a government agency, the FDA has limited flexibility to reinvent itself. According to an unnamed high-level official, "People need to calm down. We're doing the best we can. With FDA, we've pretty much sucked pharma dry. Until the public is willing to fund the agency properly, we're all s__t out of luck. Under the circumstances, we think this deal is the public's best option."

An anonymous telephone caller, claiming to be from the CRO, explained the CRO's strategy: "The FDA has scientists; we have scientists. They study drugs; we study drugs. But as a privately-held corporation, we're not subject to endless second guessing by media, legislators, pharmaceutical companies, patient advocacy groups, and any other loose cannon who wants to put their oar in. Instead of spending all our time justifying our existence, we can actually get the work done. For us, it's all about helping people live longer, healthier, happier lives."

"As a full-service CRO with global operations, this move is the natural next step for us. If we're not welcome here, there are plenty of other countries around the world that would bend over to have us. We are already in discussions with the regulatory authorities in some other countries about franchising opportunities. God knows the EU needs help." Because the telephone caller refused to identify himself, his information should be taken with a grain of salt, preferably at mealtime.

The CRO will also obtain a 12-month option to acquire the FDA's Center for Biologics Evaluation and Research (CBER). The anonymous caller commented, "We see real growth opportunities, although biogenerics are like a total wild card."

Financing for the transaction has been lined up from Temasek Holdings, Singapore's sovereign wealth fund, and other unidentified sources. According to a Temasek spokesperson, "The FDA is the regulatory gold standard. Recently, gold has worked a lot better for us than dollars."

The future of FDA's Center for Devices and Radiological Health (CDRH) is still under discussion, but may be taken private in a management buyout organized by the Blackstone Group. A company spokesperson admitted that discussions were underway: "Now that we are a public company, serving the needs of the medical device industry is within our charter. Besides, General Electric may think twice about not playing ball on our next deal."

The FDA's cosmetics responsibilities will be spun off to French conglomerate LVMH Moët Hennessy Louis Vuitton. According to a high-level FDA official who preferred to remain anonymous, "I thought that guy left. Whatever. The French are on our side again, right?" The LVMH transaction is contingent on approval from 27 congressional committees with homeland security oversight. As a "Plan B," discussions are also underway with cosmetics retailer Sephora.

These divestitures will permit the agency to dedicate its full attention to regulating food products. Current plans are to rename the agency the "Food, Beverage and More!"

Administration.” According to an inside source, the dietary supplement industry is off limits until after the elections. Even then, “probably the best we can do is couponing.”

The parties had hoped to announce the transaction today – April 1st – but concerns were expressed that the public would think it’s all just a big April Fool’s joke. A new announcement date has not been determined.

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