

# APPROVAL!!

## How It All Came Down

By John Fitchen, *EPT Newswire*

It's Christmas night. All the presents have long since been opened, we've been to the traditional neighborhood party, the kids are upstairs trying out new video games, Ellen's asleep on the sofa. It's quiet, peaceful even. And there is finally a moment to reflect on what's happened in the last four days, to relive the events and the emotions surrounding the approval of OraSure, to share it with all of you who made it happen.

I guess it began early Wednesday morning when Al and Kevin and I met at 5:45AM at the Portland Airport. Over coffee we speculated about the meaning of the quickened pace with the FDA, about the rumors that they wanted to get it done by Christmas.

"I'll believe it when I see the approval letter," I said. "I know," said Al, "but this time it's different. Not only is there a sense of all-out effort at Epitope, there's a sense of all-out effort at the Agency, too, not to mention the faxes and phone calls between FDA and Organon. This may actually happen, and if it does, we've got to get ready."

We talked on the plane about the plans that had been made. About setting up the special phone line for the media, the various possible venues for a short-notice press conference, the outside experts list, the code words for communicating with Andy if we got the word.

When we arrived in Pennsylvania, I called Elaine. She was camped out in D.C. and had been in almost hourly contact with Sharon Geyer and others at the FDA. She rattled off a long list of minor changes in labeling and SOPs that the Agency wanted finalized overnight.

"Do they need final, mastered documents or just Change Requests?" I asked. "They want the final, official paper," Elaine said, "signed, sealed and delivered."

"Can we do it?" I asked. "Well, everybody is willing to stay up all night if that's what it takes," she told me. "We'll give it a shot."

Next, I called Tom Clement, the Reg. Affairs director at Organon, to see if he had received the marked up version of their package insert from Sharon Geyer. He told me he finally had (he had originally expected it Tuesday), and there were problems. "She wants to require that calibration readings are specified in the package insert and recorded by every laboratory each time they test OraSure samples," he told me. But there was good news on the sample adequacy language. FDA had apparently accepted our arguments and had softened its position on this potential sticking point.

Al, Kevin, Gil (who had hooked up with us on his way back from Europe) and I headed off to dinner with

our hosts, knowing that they would ask about the timing of approval and wondering what we should say. We didn't say much.

The next day (Thursday), we were holed up in a conference room talking future business with our hosts when the phone rang. It was Deb Auter, associate of Nancy Buc, our regulatory counsel in Washington. "FDA wants a conference call with you guys and Nancy at 3:30 to discuss conditions of approval," Deb told us. "Nancy's on the Jersey Turnpike on her way back from New York, but we can patch her in on her cell phone."

We asked the people around the conference table if we could have a few minutes to huddle. A 3:30 conference call was going to be touch and go because we had a 5:00 o'clock plane to catch. Gil called Jan Misley. If we needed more time, we could get an 8:00PM flight to Seattle.

Deb Auter called back and said FDA wanted more time—could the conference call be at 4:30 or 5:00. Gil alerted Jan to switch us to the later flight, and we headed off to the airport where our hosts had lined up a conference room with a speaker phone. The setup was fairly primitive: there was an adequate speaker phone, but the pay fax machine was outside the conference room and the instructions were hard to understand (at least for a bunch of excited executives).

Finally the FDA cover sheet came through on the fax machine. But that was it—cover sheet and nothing else. We thought the machine had run out of paper. Thirty minutes later we finally found someone who could help us. It turned out the rest of the pages were rolled up inside the machine.

Knowing that the conference call was about to begin, we powered through the conditions listed in the fax. No surprises. A few questions of information, but no key issues. Having waited until the last possible minute, Kevin said he had to split to catch his plane to his mom's. As he zipped out the door, he dead-panned, "This looks pretty good."

We got through to Nancy Buc on the Jersey Turnpike. "Is there anything here we can't live with?" we asked her. "No, this is great! This should be it," she told us.

Five minutes later the phone rang. "ATT operator with a conference call for Mr. Ferro. Let me take the roll call please." The operator ticked off the people on the call—Al Ferro; Nancy Buc; Kathy Zoon, Jay Epstein and others (from CBER), Mary Pendergast and Amanda Pedersen (from the Commissioner's Office).

We asked a few questions about the conditions. It was clear there was nothing serious in our way. Nancy Buc chimed in. "Not to be presumptuous, but does this mean we can expect a letter in the near future?" FDA was evasive. "You understand, don't you, that Al is on

the East Coast and that Epitope is closed tomorrow." Oh, no, they didn't understand that. Maybe it would be a good idea if Al got back to Oregon tonight because there might be something in the morning. "How early in the morning? We have to make a coordinated announcement in keeping with SEC rules and guidelines."

FDA said they didn't know about stock-related issues, but finally told us they might issue a letter and a simultaneous public statement as early as 7:00AM East Coast time (4:00AM in Oregon). Al gave FDA his home phone number and requested a call if anything was going out before 6:00AM Pacific time. Everybody expressed positive, mutual effort sentiments as the conference call came to a close.

Al, Gil and I took a deep breath. We had about an hour before we had to catch our plane. Gil checked our tickets and suddenly realized that we (and our luggage) were only booked through to Seattle. He went to call Jan.

Al and I called Steve Weiner, our PR/Media consultant in Chicago. "Can you make it to Portland tonight?" we asked him. "Yeah, there's a 9:30 out of O'Hare," he said, "I should be able to catch that." We agreed that we would all meet at Epitope at 6:00AM. Steve asked if we had notified anyone at the company yet. "We called you first because we knew you had to make travel arrangements, but we're about to call Andy and inform Mary so that the necessary actions can get in motion back there," we told him.

When we reached Andy, the Epitope Holiday Party was in full swing. "Are you sitting down? Are you alone?" we asked Andy. "Better close your door. We have good news. *THE EAGLE HAS LANDED!*" Andy immediately recognized the code words (a modification of what we had planned in the event that word was received at Epitope while we were away). "This is fantastic," he said, "Wow!" "Gotta talk quietly," we said, "This is very sensitive information." Andy told us the party was still going and nobody could hear. We all fantasized about how neat it would be to patch into the PA system and announce the news at the party. Alas, per SEC rules about selective disclosure, that couldn't be. Andy went to get Mary so that media arrangements could be set in motion.

Al and I looked straight at each other. Eye to eye we realized that this was it. This was the moment, the eye of the needle, the fulcrum. Approval! We talked about how we shouldn't tell anyone, not even our families, until the news was public. That lasted about two minutes. Al got through to home. Julie was out; Jay was there. With tears streaming down his cheeks, he told his son the happy news. "This is it, Jay, we're off and running now."

Five minutes later I reached Ellen and told her about the "eagle." She couldn't believe her ears. We agreed that she would wait until bedtime to tell the boys, for fear that they might inadvertently say something to a friend.

Our calls weren't done, but we had to get to the plane. Al, Gil and I were in the same row, and the minute we got seated, we all started writing. Lists of who to call, refinements of the press release, plans for how to orchestrate Friday. Edits of the press release, letter to stockholders, and comments to the media passed from seat to seat as we sipped airline champagne. Gil pecked furiously at his portable computer.

When we reached our cruising altitude, Al called Roger Pringle on the Air Phone so that Roger could pass the word to the Board of Directors. As soon as he was off

the phone with Roger, Al asked me to call Kevin. I glanced at the businessman sitting next to me. His eyes were half closed, but I was sure he would hear me talking on the phone. "You better make the call," I said to Al, who was sitting on the other side of Gil next to the window. Al got Kevin at his mother's and told him that things did, indeed, look pretty good. "I want you to activate plans for product roll-out immediately."

We touched down in Seattle on time, relieved that we would make our connection to Portland. Our luggage was another story. Our bags, we were told, had been originally checked through to Seattle, then (hopefully) flagged to go to Portland. We decided to go to the baggage claim in Seattle to see if they turned up there. Gil went to the gate to check us in while Al and I waited. Al's bag and one of Gil's bags popped up. Al headed off with what we had received. I waited. At five minutes before departure, I ran the half-mile to the gate only to find that our flight was delayed—I would make it to Portland, but the arrival of the rest of our luggage would have to rest on providence.

We were met at the Portland Airport by Julie and Jay Ferro and Peggy Miller. Miracle of miracles, and in keeping with the feeling that God was on our side, the missing luggage rolled out at baggage claim.

I pulled up the driveway at 1:05AM. Marty (my 12 year-old, who I expected to be long since fast asleep) called out his window, "Way to go, Dad!" And Matthew charged out the door and embraced me in a big bearhug.

I stayed up until 2:30AM talking with my family about what had transpired. The alarm clock went off at 4:30 and for once it was easy for me to bounce right out of bed. It was coming down today.

We congregated at 6:00AM. Al had received a call at 5:30AM from Kathy Zoon and Jay Epstein saying the letter was signed and was being faxed. It hadn't yet arrived. What's going on, we wondered. AMEX had been notified that we were anticipating a major announcement and wondered if trading in our stock should be halted. AMEX demurred, but then decided to halt trading on their own because of an uptick in activity.

We called FDA to ask what was happening. The word was that the letter was coming but had to be "date-stamped and logged out," and that this process might take another hour or two. Then finally, somewhere around 7:30AM our time, the approval letter came. We sat down and read it fast but carefully. Nothing new; no surprises. The press release was a "go".

We put out the news. AMEX endeavored to reopen trading, somewhere in the 24 to 28 range. I told Katharine to spread the word, and a most remarkable phenomenon began to happen—people just showed up. As the media blitz swirled, the people of Epitope appeared; and smiled, and cheered, and gave us hugs. As we struggled with how to deal with difficult questions from the media, we were buoyed by what was happening. A spontaneous celebration, a joyous expression of victory was going on around us. Everybody was hugging; hugging us, hugging each other. We headed off to the press conference feeling the emotional support of the whole company.

The rest, as they say, is history. The front-page article by Mike Francis in the Saturday *Oregonian*, and then, amazingly, more front-page coverage on Sunday, was incredible and gratifying. I feel tonight like a great thing has happened. I feel like David has overcome Goliath. I'm proud for all of us, and I'm excited by what lies ahead.