

Butler, Jennie C

From: SRPeltier@aol.com
Sent: Thursday, June 13, 2002 10:37 AM
To: FDADockets@oc.fda.gov
Subject: [02N-0169] Combination Products Containing Live Cellular Components Hearing
Notice of Participation for:

Steven R. Peltier
VP Clinical and Regulatory Affairs
Ortec International, Inc.
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New York, NY 10032
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The presentation will cover an introduction to Ortec International, Inc. and detailed responses to the questions raised in the Notice of Public Hearing. We will express our concern regarding the potential change in jurisdiction for these products, our experiences with CDRH and the philosophy that is embodied within CDRH which allows for the least burdensome, predictable, timely, flexible, transparent, interactive, and effective review of these products. Overall we should require no more than 10 minutes.

Steven R. Peltier RAC
VP Clinical and Regulatory Affairs
Ortec International, Inc.

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