CONFIDENTIAL
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OFFICE OF THE COMMISSIONER MEETING
EXECUTIVE SUMMARY

Date: May 12, 2009
Time: 9:15 a.m.
Location: [redacted] – can you provide the location and the attendees, please?]
Subject: Regulation of Compounded Human Drugs

Attendees:

Purpose: The briefing's purpose is to request the Acting Commissioner's support for a plan to clarify FDA's authority over compounded human drugs in the aftermath of two court decisions that addressed FDA's authority to regulate pharmacy compounding under FDCA section 503A.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Options/Recommendations:

[redacted]

[redacted]

[redacted]

[redacted]