July 7, 2009

MEMORANDUM TO: Michael T. Lesar, Chief
Rulemaking and Directives Branch
Division of Administrative Services
Office of Administration

FROM: Mark S. Delligatti, Chief
Rulemaking Branch B **/RA/**
Division of Intergovernmental Liaison
and Rulemaking, FSME

SUBJECT: DIRECT FINAL RULE: REVISIONS TO PART 35, MEDICAL USE OF BYPRODUCT MATERIAL- AUTHORIZED USER CLARIFICATION (RIN 3150-AI59)

On June 26, 2009, the EDO approved and signed the direct final rule (ML091630135) and companion proposed rule (ML091630141) on the above subject.

Please implement the EDO's action by arranging for publication of the attached direct final rule and proposed rule in the *Federal Register*. The notice to the Commission indicates that the direct final rule should not be forwarded to the Office of the Federal Register (OFR) before July 7, 2009.

Attached are the Congressional Letter package ML091870596 and the Congressional Review Act (CRA) forms for transmittal to the Office of Congressional Affairs. Please coordinate the publication of the press release with the Office of Public Affairs.

Please note that OFR needs to add the effective date and the public comment closing date to pages 2 and 10 of the direct final rule and to pages 2 and 4 of the companion proposed rule.

Enclosures:
1. *Federal Register* Notice of Direct Final Rule + 17 Copies
2. *Federal Register* Notice of Proposed Rule + 17 Copies
3. Congressional Letters
4. CRA forms

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