HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION[1]

Title: Initial Caps for Significant Words, No Period after the Title

Significance of Regulation[2]: Two choices: "Not Significant under Executive Order 12866" or "Significant under paragraph [insert ¶ number] of Executive Order 12866 § 3(f)".[3] If the action is a Final Rule, add "The proposed rule was classified as [insert either "Significant" or "not Significant"] on OMB List [insert list number]."

**normally, if an ANPRM or NPRM was "Significant", the subsequent FR will be "Significant". If you think the FR is "Not Significant", state why.

ex: "Significant under paragraph 4 of Executive Order 12866 § 3(f). The proposed rule was determined to be "Significant" on OMB List 39."

ex: "Not significant under Executive Order 12866. Although the proposed rule was deemed significant on OMB List 19, the proposal did not raise any controversial issues, and the agency did not receive any significant adverse comments. Therefore, the final rule is virtually identical to the proposal."

HHS Review[4]: State (in a sentence or two) whether HHS review is warranted [i.e., whether it is important, sensitive, controversial, precedent setting, etc.].

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[1] Write-ups are due to the Department one month before the beginning of each quarter. Include all rules expected to be cleared by FDA by the end of the next quarter (i.e., within 6 months after the write-up is due).

[2] exemptions [E.O. 12866 §3(d) and *Guidance for Implementing E.O. 12866* Appendix C]:

1. regs under 5 U.S.C. §§556, 557 (formal rulemaking hearings)
2. regs pertaining to a military or foreign affairs function of the US (other than procurement...)
3. regs limited to agency organization, management, personnel matters
4. other categories exempted by OIRA
5. agency notices of funds availability
6. medical device reclassifications to less stringent categories
7. OTC monographs, unless they may be precedent-setting or have large adverse effects on consumers
8. Final rules for which no comments were received and which do not differ from the NPRM

[3] E.O. 12866 §3(f): "Significant regulatory action" means any regulatory action that is likely to result in a rule that may:

(1) have an **annual effect on the economy of $100 million or more** *or* **adversely affect in a material way the economy**, a sector of the economy, productivity, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
(2) create a **serious inconsistency** or otherwise interfere with an action taken or planned by another agency;
(3) **materially alter the budgetary impact** of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
(4) raise **novel legal or policy issues** arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

[4] Things specifically exempt from HHS review **if routine in nature** (*not exempt if they may cause controversy or become of particular interest to outside parties such as the press or Congress*):

1. device classifications - which *category* of control covers a particular device
2. regs stating the *effective date* for required premarket approval applications of certain class III medical devices
3. regs containing *OTC monographs*

ex: "HHS review is warranted because this final rule impacts the entire human cell, tissue, and cellular and tissue-based product industry."

ex: "HHS waived review of the NPRM."
ex: "Not warranted. These are purely technical amendments."

Upcoming Action: Options include "Advanced Notice of Proposed Rule Making", "Notice of Proposed Rulemaking", "Proposed Rule", "Direct Final Rule", "Final Rule", "Interim Final Rule", etc.

RIN: 0910-????.[5] **FRDTS No.:** self-explanatory.[6]

Statutory/Judicial Deadline: Indicate "None" or insert date of the statutory or judicial deadline. Any deadline should be verified by the appropriate OCC/Division leader.

Purpose: Insert a clear and concise statement (~one paragraph) of why the regulation is being issued and/or what it is expected to accomplish.

Description: Insert a clear and concise statement (less than one page) of exactly what the regulation will do and, if relevant, how it will do it.

Issues: Briefly describe potential controversy; legal or policy issues; statutory requirements; whether the regulation was drafted in response to a petition, a court order, or a Congressional directive; the extent of administrative discretion allowed by the statute in addressing issues; etc. This section is also a catch-all for any interesting/useful information that doesn't fit elsewhere.

Impact: Identify, and quantify if possible, both costs and benefits, briefly describing who will be affected, how, and to what extent (if known). Issues include who wins, who loses, who cares; congressional concerns; impact on non-HHS programs; impact on small businesses; impact on State, local or tribal governments; and why this action is important, sensitive, controversial, or precedent setting.

Budget Implications: Indicate "None" or include an explanation (limited to implications for FDA) of effect on outlays, number of years and awards, administrative overhead, or other relevant measures. May include savings as well as costs.

ex: "FDA estimates the first year implementation to cost $5 million (FY 2005)."

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4. final rules for which *no substantive comments* were received on the NPRM and which are substantially similar to the NPRM [on a *case by case* basis: FDA will notify HHS about these final rules a day or two before they are forwarded to the OMB for review or the OFR for publication so that HHS can determine if its review is warranted].

[5] "RIN" is the Regulation Indentifier Number published in the Unified Agenda/Regulatory Plan. If a RIN has not been assigned, the Center/Office should obtain one by contacting RPMS. OMB requires a RIN for documents they review.

[6] Obtain number through FRDTS contact in Center/Office.

Paperwork: Indicate "None" or explain paperwork burdens imposed by the regulation, including positive and negative effects.[7]

ex: "The proposed rule would impose additional reporting and record keeping requirements, a paperwork burden estimated at [insert number of] hours. The document will include a burden chart and solicit comments on these proposed requirements."

ex: "Based upon the number of Adverse Experience Reports submitted to the agency from 1987 to 1995, we estimate an average reduction of approximately 225 reports per year."

ex: "The proposed rule imposes a labeling requirement, which is a third party disclosure subject to review under the Paperwork Reduction Act. A package on the information collection requirements will be submitted to OMB for approval."

SBREFA: Indicate "This is not a major rule", or describe how it meets the criteria for what is a major rule under SBREFA[8].

ex: "Because expenditure could exceed $300 million, this rule is a major rule."

Federalism Implications: "None" or describe.[9]

Public Comments: For actions providing a comment period, include the length of the comment period. For actions where a public comment period was previously provided, include a brief statement of the nature and extent of the major comments and the changes made, if any, in response to those comments; identify any other outreach, including that with State and local government.

ex: "The proposal will provide 90 days for public comment."

ex: "The agency received four comments on the proposed rule. The comments did not result in any changes to the final rule."

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[7] A "paperwork burden" is any **collection of information** from **10 or more persons**. A collection of information is asking identical questions to ten or more persons, whether the response is mandatory, voluntary, or required to obtain or retain a benefit. It can be in any format (e.g., survey, telephone call, etc.). Any recordkeeping, reporting, or disclosure requirement contained in a rule of general applicability is deemed to involve ten or more persons. (5 CFR 1320.3(c)(4)(i)).

[8] Under SBREFA [5 U.S.C. § 804(2)], a "major rule" is defined as a rule that has resulted in or is likely to result in--

(A) an annual effect on the economy of $100,000,000 or more;

(B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; *or*

(C) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

[9] E.O. 13132 defines "Federalism implications" as actions that "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

ex: "FDA received over 35 comments on the proposed rule, which resulted in the following revisions: [list revisions] …"

Regulation Roll-Out: Three choices: "Not recommended at this time", "To be determined", or "Recommended. [State reason]".

ex: "Recommended due to recent interest from the Press and Congress."

Contact Person: [Insert name of RPMS Desk Officer responsible for the document], Office of Policy, Regulations Policy and Management Staff, 301-827-3480.

****Notes**:

- Insert 2 spaces after colons and periods.
- Write-ups should be clear, concise, and brief (not exceeding 2 pages total).
- Omitted or incomplete items will delay the process.
- If you have any questions about the list process (e.g., where to find the OMB list number), contact Darlease Hyman at RPMS

HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Title: Type Over This With Real Title (Title Case, No Period After)

Significance of Regulation: (select)

HHS Review: (select)

Upcoming Action: (select)

RIN: 0910-???? **FRDTS No.:**

Statutory/Judicial Deadline: None.

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Impact: Indentify, and quantify if possible, both costs and benefits, briefly describing who will be affected, how, and to what extent (if known).

Budget Implications: None.

Paperwork: None.

SBREFA: (select)

Federalism Implications: None.

Public Comments: Insert description: length of period or type of comments/ changes made.

Regulation Roll-Out: (select)

Contact Person: (select contact person), Office of Policy, Regulations Policy and Management Staff, 301-827-3480.

APPENDIX 6: OMB Write-up Template