

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0514]

Draft Guidance for Industry on ANDA's: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDA's: Impurities in Drug Substances." This draft guidance provides recommendations for including information in abbreviated new drug applications (ANDA's) and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances.

DATES: Written comments on the draft guidance may be submitted by September 22, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm". Written requests for single copies of the draft guidance for industry should be submitted to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert W. Trimmer, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD-625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-5848.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "ANDA's: Impurities in Drug Substances." This draft guidance provides information on the following: (1) Qualifying impurities found in the drug substance used for ANDA via a comparison with impurities found in the related United States Pharmacopeia (USP) monograph, scientific literature, or innovator material; (2) qualifying impurities found at higher levels in the drug substance used for ANDA than found in the related USP monograph, scientific

literature, or innovator material; (3) qualifying impurities in the drug substance used for ANDA which are not found in the related USP monograph, scientific literature, or innovator material; and (4) threshold levels, below which qualification is not needed.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the content and qualification of impurities in drug substances produced by chemical syntheses that are used in generic drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may, on or before September 22, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-250,254]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper

performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Secondary Payer Information Collection and Supporting Regulations 42 CFR 489.20; *Form No.:* HCFA-250,254 OMB #0938-0214; *Use:* This questionnaire will collect information from beneficiaries on health insurance coverage that is primary to Medicare. This information is necessary in order for HCFA to identify those Medicare beneficiaries who have group health insurance that would pay before Medicare, resulting in savings to the Medicare Trust Fund. Medicare Secondary Payer (MSP) is essentially the same concept known in the private insurance industry as coordination of benefits, and refers to those situations where Medicare does not have primary responsibility for paying the medical expenses of a Medicare beneficiary. HCFA contracts with health insuring organizations, herein referred to as intermediaries and carriers, to process Medicare claims. HCFA charges its Medicare intermediaries and carriers with various tasks to detect MSP cases; develops and disseminates tools to enable them to better perform their tasks; and monitors their performance in achievement of their assigned MSP functions. Because intermediaries and carriers are also marketing health insurance products that may have liability when Medicare is secondary, the MSP provisions create the potential for conflict of interest. Recognizing this inherent conflict, HCFA has taken steps to ensure that its intermediaries and carriers process claims in accordance with the MSP provisions, regardless of what other insurer is primary. *Frequency:* One time only; *Affected Public:* Individuals or Households; *Number of Respondents:* 14,204,000; *Total Annual Responses:* 14,204,000; *Total Annual Hours:* 773,240.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcf.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed