

consultation with the FDA and experts in pediatric research shall develop, prioritize, and publish an annual list of certain approved drugs for which pediatric studies are needed. For inclusion on the list, an approved drug must meet the following criteria: (1) There is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); (2) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act; (3) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or (4) there is a referral for inclusion on the list under section 505A(d)(4)(c); and additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

The BPCA further stipulates that in developing and prioritizing the list, the NIH shall consider, for each drug on the list: (1) The availability of information concerning the safe and effective use of the drug in the pediatric population; (2) whether additional information is needed; (3) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and (4) whether reformulation of the drug is necessary.

In developing this initial list, the NIH consulted with the FDA, the American Academy of Pediatrics, the United States Pharmacopoeia and other experts in pediatric research. A preliminary list of off-patent drugs was drafted and categorized as a function of indication and use. The drugs were then prioritized based on frequency of use in the pediatric population, severity of the condition being treated, and potential for providing a health benefit in the pediatric population.

*Following is the list of drugs for which pediatric studies are most urgently needed:*

Azithromycin  
Baclofen  
Bumetanide  
Dobutamine  
Dopamine  
Furosemide  
Heparin  
Lithium  
Lorazepam  
Rifampin  
Sodium Nitroprusside  
Spironolactone

Dated: January 9, 2003.

**Ruth L. Kirschstein,**  
*Deputy Director, NIH.*

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4820-N-02]

### Notice of Proposed Information Collection: Comment Request; Builder's Certification of Plans, Specifications, and Site

**AGENCY:** Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** *Comments Due Date:* March 24, 2003.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposed by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, L'Enfant Plaza Building, Room 8003, Washington, DC 20410 or [Wayne\\_Eddins@hud.gov](mailto:Wayne_Eddins@hud.gov).

**FOR FURTHER INFORMATION CONTACT:** Vance Morris, Director, Office of Single Family Program Development, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, telephone (202) 708-2121 (this is not a toll free number) for copies of the proposed forms and other available information.

**SUPPLEMENTARY INFORMATION:** The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of

information technology, e.g., permitting electronic submission of responses.

This Notice also list the following information:

*Title of Proposal:* Builder's Certification of Plans, Specifications, and Site.

*OMB Control Number, if applicable:* 2502-0496.

*Description of the need for the information and proposed use:* HUD requires the builder to complete the certification (form HUD-92541) noting adverse site/location factor(s) of the property, including Floodplains. This certification is necessary so that HUD does not insure a mortgage on property that poses a risk to health or safety of the occupant.

*Agency form numbers, if applicable:* HUD-92541.

*Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:* The estimated total number of hours needed to prepare the information collection is 16,400; the number of respondents is approximately 800 generating approximately 65,600 annual responses; the frequency of response is on occasion; and the estimated time needed to prepare the response varies from 5 minutes to 10 minutes.

*Status of the proposed information collection:* Extension of a currently approved collection.

**Authority:** The paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Dated: January 13, 2003.

**John C. Weicher,**

*Assistant Secretary for Housing-Federal Housing Commissioner.*

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4728-N-02]

### Notice of Certain Operating Cost Adjustment Factors for Fiscal Year 2003

**AGENCY:** Office of the Secretary, HUD.

**ACTION:** Publication of the 2003 Operating Cost Adjustment Factors (OCAFs) for Section 8 rent adjustments at contract renewal under section 524 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA), as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of 1999, and under the Low-Income Housing Preservation and