understanding of current practices in handling such cases.

Comment: Comments regarding the grants to private voluntary organizations questioned the funding for other than direct services, the dollar limit on each award, the clarity of the application package, and the practice of making the awards on a first-come, first-served basis.

OJJDP Response: OJJDP's grants to private voluntary organizations, following the specific requirements of section 406(a), support a variety of programs related to missing and exploited children, including, but not limited to, those which provide direct services to child victims and their families. The dollar amount available to each eligible organization will continue to be limited to a maximum of $25,000 in order to enable a greater number of sites to receive the grants. The grant application process was simplified to minimize the burden on private voluntary organizations applying for the funds. Finally, applicants will continue to be required to provide both specific documentation on financial and administrative matters and letters of support from district attorneys or judges in their communities. Once this documentation is included and the application meets the program and budget criteria for an eligible program, the money is awarded to qualified organizations until the designated funds are exhausted.

Comment: The role of the National Center for Missing and Exploited Children as a direct service provider and central authority, as well as the function of its toll-free telephone line, was questioned.

OJJDP Response: Established as a national clearinghouse and resource center, the purpose of the National Center is to provide technical assistance, disseminate information and coordinate programs relating to missing and exploited children, not to provide direct services. Their ability to serve as a central authority for the reporting of all missing child cases is dependent upon the willingness of the other parties involved to supply them with the appropriate information.

The Center has no control over the types of incoming calls made to their toll-free number. They receive requests for information, as well as calls reporting child sightings and disappearances. In the interest of delivering the best possible advice regarding missing children, the Center provides technical assistance and informational materials and make appropriate referrals. Such procedures are consistent with the statute that provides "* * * individuals may * * * request information pertaining to procedures necessary to reunite such child with such child's legal custodian" (Section 404(b)(1)).

Dated: June 14, 1988.

Approved.

Diane M. Munson,

Acting Administrator, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 88-13792 Filed 6-17-88; 8:45 am]

BILLING CODE 4410-18-M

federal register

Monday
June 20, 1988

Part III

Department of Justice

Office of Juvenile Justice and Delinquency Prevention

Program Announcement; Reunification of Missing Children; Notice

DEPARTMENT OF JUSTICE

Office of Juvenile Justice and Delinquency Prevention

Program Announcement; Reunification of Missing Children

AGENCY: Office of Juvenile Justice and Delinquency Prevention, Justice.

SUMMARY: The Office of Juvenile Justice and Delinquency Prevention (OJJDP), pursuant to section 406(a)(2) and (4) of the Missing Children's Assistance Act, Title IV of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended, announces a new OJJDP development initiative to assess, develop, test and disseminate information on prototypical approaches for the Reunification of Missing Children with their families.

The purpose of the development initiative is to identify promising or effective strategies to assist families in adjusting to the return of a missing child.

OJJDP invites public agencies or nonprofit private agencies, or combinations thereof, to submit competitive applications to develop prototypical (model) approaches to reunifying missing children with their family. The development program includes four stages: (1) Identification and assessment of existing information on child/family relationships in stressful situations and selected programmatic approaches; (2) prototype (model) development based on the assessment; (3) development of training and technical assistance materials to transfer the prototype design; and (4) testing of the prototypes.

OJJDP has allocated up to $175,000 to conduct the first two stages which are to be completed in nine (9) months. Assessment Stage—5 months; Prototype Stage—4 months. The initial budget period will be for nine (9) months. Upon completion of the prototype, a decision will be made regarding support for the last two stages. The project period may go up to three years. One cooperative agreement will be awarded. Applicants are encouraged to present cost-competitive proposals.

The deadline for receipt of applications is July 27, 1988.

FOR FURTHER INFORMATION CONTACT: Lois T. Keck, Research and Program Development Division, (202) 724–7560 or Robert Heck, Special Emphasis Division (202) 724–5914, OJJDP, 633 Indiana Avenue NW., Washington, DC 20531.

SUPPLEMENTARY INFORMATION:

I. Introduction

This solicitation to develop prototypical approaches to the Reunification of Missing Children is issued by the Office of Juvenile Justice and Delinquency Prevention (OJJDP). The solicitation addresses the Missing Children's Assistance Act that authorizes the Administrator of OJJDP to: make grants to and enter into contracts with public agencies or nonprofit private organizations, or combinations thereof, for research, demonstration projects or service programs designed to provide information to assist in the locating and return of missing children. Title IV, sections 406(a)(2) and (4).

Many efforts focused on missing children have been dedicated to the location of these children. Comparatively little attention has been given to the creation of support services to aid families in readjusting to the return of a missing child. The problem of reunifying children who have been missing with their lawful custodians is complex. Based on our review of the literature, little research has been conducted specifically on this issue.

One empirical study on the return of missing children was done by Lenore C. Terr (1981). She presented a detailed review of the Chowchilla School-Bus Kidnapping. Her findings and theoretical speculations indicated that every child involved in the kidnapping showed signs of emotional psychic trauma. However, she provided no recommendations for assisting the families in adjusting to the return of the children. Her study was primarily a descriptive one that placed emphasis on data gathering and understanding what happened to the children while missing. The mere opportunity for the children to review and describe the entire chain of events within the first year following the incident may have afforded the victims and their families some minimal emotional relief. However, based on her findings four years later, these efforts had not been particularly effective in preventing post-traumatic symptoms in the children. This is but one of the many aspects of family reunification that needs to be examined.

This program is designed to develop prototypical policies and procedures for law enforcement, social services and other relevant programs for reunifying missing children with their families, as well as provide information that may assist families in identifying support services.

II. Program Goals and Objectives

A. Goals

1. To increase understanding of the factors that need to be addressed in reunifying missing children with their families;

2. To identify promising strategies that assist families in adjusting to the return of a missing child, including the adjustment of siblings as well as parents.

3. To identify support services, if any, that have been provided by agencies involved in returning missing children (i.e., law enforcement, mental health, missing children's centers).

4. To identify techniques to assist custodial parents with the reunification of a returned child whose appearance and personality have changed or a returned child who was given negative information about the other parent.

5. To improve the capability of law enforcement, social services and other community agencies to effectively reunify missing children with their families.

B. Objectives

1. Assess existing information regarding the reunification of missing children, and reunification approaches that address the needs of families of missing children, develop criteria for identifying promising approaches, and review and describe operational promising programs;

2. Develop prototypes based on research and the assessment of selected operational programs;

3. Develop a dissemination strategy and related training and technical assistance materials to transfer the prototypes to selected sites; (Applicants are advised that this stage of the program development initiative will not be funded during the initial budget period); and,

4. Test program prototypes; (Applicants are advised that this stage of the program development initiative will not be funded during the intitial budget period).

III. Program Strategy

OJJDP's planning and program development activities are guided by a framework that specifies four sequential phases of development: Research, Development, Demonstration and Dissemination. This framework guides the decision-making process regarding the funding of future stages of the program.

This program is a development initiative. The purpose of the development initiative is to develop

prototype/models and to determine their effectiveness through a controlled testing process. The program will be conducted in four discrete incremental stages. The four stages include: (1) An assessment of the information on return and reunification of missing children and child/family relationships in stressful situations; (2) a comprehensive description of the development, implementation and operation of prototypical programs; (3) the development of a training and technical assistance package in order to provide intensive training to test sites that are implementing the prototype; and (4) testing of the prototypes. During the 9-month budget period, it is expected that stages one and two will be completed.

All technical and subject matter portions of the program will be guided by recommendations of an advisory committee established specifically for the program. The advisory committee will provide comments and recomendations regarding the strategies and activities for this program. It may be necessary to change or supplement advisory committee members for different stages of the program; however, the objective will be to select technical and subject matter experts capable of addressing issues related to each of the program states. The advisory committee members should have combined expertise in juvenile justice system research and evaluation; training and technical assistance development and delivery; and knowledge of missing and exploited children, family counseling, crisis intervention, and psychological assessment of stress and traumatization.

Each stage of the incremental program development process detailed below is designed to result in a complete and publishable product (e.g., final assessment report), and a dissemination strategy to inform the field of the development of the program and the results and products of each stage. This award is providing funds for stages I and II. A decision is made at the completion of each stage, based on availability of funds, and the quality and utility of the products, whether to invest additional funds to complete the current stage or terminate the program.

A. Stage I—Assessment

The first stage of the program consists of an assessment that will include: (1) A literature review to identify significant issues and problems involved in the reunification of missing children; (2) a summary of the types of families who seek treatment toward reunifying their family and the system's response to these families; (3) identification of the essential components of an effective approach to reunification of missing children; and (4) preliminary testing design guidelines for use in the testing phase.

The purpose of the literature review is to identify the most definitive theoretical and empirical research findings in order to appy them to the review of existing programs, and the development of prototypical model(s).

The recipient will apply the results of the literature review to the development of criteria for identifying promising approaches to reunification of missing children, and use the criteria to select programs for review and documentation. Information to be collected and assessed should include, at a minimum, the historical development of the programs; conceptual framework/theoretical assumptions, definition of the target populations and subsequent system services for the families; identification of services and treatment modalities; number and type of families served; program costs per unit of service and per client; evaluation findings, if applicable; sources of funding; staffing requirements; and program approach to management and administration.

The assessment should provide the basis for refining the goals and objectives of the development program. Specifically, it should identify the key questions that need to be answered regarding the feasibility and effectiveness of the program. Therefore, based on the literature review and the results of the program assessment, the recipient will recommend specific programs or components of programs to be used as a basis for program prototype development.

1. Activities

The major activities of this stage are:

- Establishment of a program advisory committee;
- Development of the assessment plan;
- Review of the literature;
- Development of criteria for identifying promising programs;
- Identification and description of operational promising programs;
- Development of preliminary testing design guidelines;
- Preparation of the assessment report; and
- Development and implementation of a dissemination strategy.

2. Products

The products to be completed during this stage are:

- Assessment Plan—specifying in detail, the approach and activities to be undertaken for each step of the assessment stage;
- Draft and final report on the results of the assessment that includes:

—Literature review;
—Criteria for identifying promising programs;
—Description of operational promising programs and approaches;
—Recommendations for refining the goals and objectives of the program;
—Recommendations for developing prototypical/model approaches; and
—Preliminary testing design guidelines.

- Dissemination strategy to inform the field of the development of the program, and the products and results of this stage.

B. Stage II—Prototype Development

Upon successful completion of stage I, and with the approval of OJJDP, the recipient will develop prototype designs for the development, implementation, and operation of programs for the reunification of missing children. The prototype designs will be accompanied by detailed policy and procedure manuals to be developed by the recipient. The activities and products of this stage will be based on the information generated by the assessment. Appropriate technical and subject matter expertise will be utilized to design the prototypes that will be based, in part, on the operational programs described in the preceding stage.

The prototype design and related policies and procedures will provide guidance regarding: identification of the appropriate target group; relationship of the program to other public and private youth-serving agencies; funding program organization and management; the philosophy and content of the intervention; resource development; program monitoring; and evaluation of program effectiveness. The prototype designs and accompanying policies and procedures manuals will be used as the basis for the development of a training and technical assistance package if stages III and IV of this initiative are funded. The information will become part of the dissemination package to be disseminated to appropriate state and local agencies, depending on the nature and auspices of each prototype.

1. Activities

The major activities of this stage are:

- Preparation of a plan for developing the prototypes and related policies and procedures;
- Development of the prototypes and related policies and procedures;

• Participation and review by the program advisory committee; and
• Development and implementation of a dissemination strategy.

2. Products

The products to be completed during this stage are:
• Plan for prototype development specifying, in detail, the approach and activities to be undertaken for each step of this stage, and the projected costs on a monthly basis;
• Draft and final prototype design(s) and related policies and procedures manual(s); and
• Dissemination strategy to inform the field of the development of the program, products and results of this stage.

C. Stage III—Training and Technical Assistance

While a decision to develop training and technical assistance materials and to test the prototype design(s) will be made during or following completion of the prototype development stage, the applicant is expected to explain the methods and approaches that would be employed to implement these stages. As noted, funds for this stage and the testing stage will be provided through non-competitive continuation awards. In order to ensure the applicant's full understanding of the entire development effort, the initial application must address and explain the implementation and coordination of all four stages of the initiative (i.e., assessment, prototype development, training and technical assistance development, and testing).

Upon successful completion of stage II, and with the approval of OJJDP, the recipient will transfer the prototype design(s), including policies and procedures, into a training and technical assistance package. A comprehensive training manual must be developed to encourage and facilitate implementation of the prototypes. The training manual must outline the major issues that need to be addressed in developing programs for the reunification of missing children, and detail program prototypes. The training manual should be the focal point of the entire training and technical assistance package. The primary audience will be policymakers and practitioners involved in resource allocation and program development related to families of missing children. The manual must be designed for a formal training setting, and for independent use in jurisdictions that do not participate in formal training sessions. Therefore, the manual should include a complete description of the prototype and incorporate related policies and procedures. The manual should contain instructions and supplementary materials for trainers to facilitate presentation, and ensure understanding and successful adaptation and implementation of the prototypes.

1. Activities

The major activities of this stage are:
• Preparation of a plan for developing the training and technical assistance package;
• Development of the training and technical assistance materials;
• Recruitment and preparation of the training and technical assistance personnel;
• Testing of the training curriculum manual;
• Participation and review by the advisory committee; and,
• Development and implementation of a dissemination strategy that may include workshops or seminars for private volunteer organizations, missing children's centers, and other practitioners involved with families of missing children.

2. Products

The products to be completed during this stage are:
• Plan for the development of the training and technical assistance package;
• Identification of training and technical assistance personnel;
• Draft and final training and technical assistance package, including the training curriculum manual and information materials; and,
• Dissemination strategy to inform the field of the development of the program, and the products and results of this stage.

D. Stage IV—Prototype Implementation and Testing

This stage of the program consists of a test, in selected jurisdictions, of the prototypes developed in stage II. The recipient will be required to assist the OJJDP in developing a solicitation to make awards to test sites. It will also be required to provide intensive training and technical assistance to help the test sites implement the prototypes on an experimental basis. Finally, the grantee will be expected to work cooperatively with an independent evaluator to ensure the integrity of the data collection and feedback activities.

1. Activities

The major activities of this stage are:
• Develop recommendations for a program announcement to select test sites;
• Assist OJJDP in review and selection of test sites;
• Provide intensive training and technical assistance to test sites regarding the implementation of prototypes on an experimental basis;
• Develop procedures for working cooperatively with the program evaluator, particularly in the areas of data collection and feedback; and,
• Develop and implement a dissemination strategy.

2. Products

The major products for this stage are:
• Recommendations for the program announcement for test sites;
• Plan for providing training and technical assistance to test sites; and,
• Dissemination strategy to inform the field of the development of the program, and the products and results of this stage.

IV. Dollar Amount and Duration

Up to $175,000 has been allocated for the initial award. One cooperative agreement will be awarded competitively, with an initial budget period of nine (9) months. This development program will consist of four stages (assessment; prototype development; policies and procedures, training, technical assistance; and testing). The initial award will provide support for stages I and II. One or more noncompetitive supplements may be awarded within a three year project period.

The noncompetitive continuation award for the additional budget period may be withheld for justifiable reasons. They include: (1) The results do not justify further program activity; (2) the recipient is delinquent in submitting required reports; (3) adequate grantor agency funds are not available to support the project; (4) the recipient has failed to show satisfactory progress in achieving the objectives of the project or otherwise failed to meet the terms and conditions of the award; (5) a recipient's management practices have failed to provide adequate stewardship of grantor agency funds; (6) outstanding audit exceptions have not been cleared; and (7) any other reason that would indicate continued funding would not be in the best interest of the Government.

A separate competition will be held to select an organization to perform an independent evaluation of the selected prototypes/models. The organization selected for this award will be ineligible to compete for the evaluation.

V. Eligibility Requirements

Applications are invited from public agencies and nonprofit private organizations. Applicant organizations may choose to submit joint proposals with other eligible organizations as long as one organization is designated in the application as the applicant and any co-applicants are designated as such. Applicants and co-applicants must demonstrate that they have prior experience in the design, conduct and implementation of research and development programs; demonstrated knowledge of issues associated with missing and exploited children; prior experience in the development and delivery of training or technical assistance; and research and evaluation of the juvenile justice system.

The applicant must also demonstrate that they have the management and financial capability to effectively implement a project of this size and scope. Applicants who fail to demonstrate that they have the capability to manage this program will be ineligible for funding consideration.

VI. Application Requirements

All applicants must submit a completed Application for Federal Assistance (Standard Form 424), including a program narrative, a detailed budget, and budget narrative. All applications must include the information outlined in this section of the solicitation (Section VI) in Part IV, Program Narrative of the application (SF–424). The program narrative of the application should not exceed 70 double-spaced pages in length.

In submitting applications that contain more than one organization, the relationships among the parties must be set forth in the application. As a general rule, organizations that describe their working relationship in the development of products and the delivery of services as primarily cooperative or collaborative in nature will be considered co-applicants. In the event of a co-applicant submission, one co-applicant must be designated as the payee to receive and disburse project funds and be responsible for the supervision and coordination of the activities of the other co-applicant. Under this arrangement, each organization would agree to be jointly and severally responsible for all project funds and services. Each co-applicant must sign the SF–424 and indicate their acceptance of the conditions of joint and several responsibility with the other co-applicant.

Applications that include non-competitive contracts for the provision of specific services must include a sole source justification for any procurement in excess of $10,000.

The following information must be included in the application (SF–424):

A. Organizational Capability

Applicants must demonstrate that they are eligible to compete for this cooperative agreement on the basis of the eligibility criteria established in Section V of this solicitation. Applicants must concisely describe their organizational experience with respect to the eligibility criteria specified in Section V above. Applicants must demonstrate how their organizational experience and capabilities will enable them to achieve the goals and objectives of this initiative. Applicants are invited to append one example of prior work products of a similar nature to their application.

Applicants must demonstrate that their organization has or can establish fiscal controls and accounting procedures that assure Federal funds available under this agreement are disbursed and accounted for properly. Applicants who have not previously received Federal funds will be asked to submit a copy of the Office of Justice Assistance, Research and Statistics (OJARS) Accounting System and Financial Capability Questionnaire (OJARS Forum 7120/1). Copies of the form will be provided in the application kit and must be prepared and submitted along with the application. Other applicants may be requested to submit this form. All questions are to be answered regardless of instructions (Section C.I.B. note). the CPA certification is required only of those applicants who have not previously received Federal funding.

B. Program Goals and Objectives

A succinct statement of your understanding of the goals and objectives of the program should be included. The application should also include a problem statement and a discussion of the potential contribution of this program to the field.

C. Program Strategy

Applicants should describe the proposed approach for achieving the goals and objectives of the development program. A detailed discussion of how each of the initial two stages of the program would be accomplished should be included. Stages three and four should be outlined.

D. Program Implementation Plan

Applicants should prepare a plan that outlines the major activities involved in implementing the program, describe how they will allocate available resources to implement the program, and how the program will be managed.

The plan must also include an annotated organizational chart depicting the roles and describing the responsibilities of key organizational/functional components, and a list of key personnel responsible for managing and implementing the two major elements of the program. Applicants must present detailed position descriptions, qualifications, and selection criteria for each position. Applicants should also provide recommendations for program advisory committee members. This documentation and individual resumes may be submitted as appendices to the application.

E. Time-Task Plan

Applicants must develop a time-task plan for the 9-month project period, clearly identifying major milestones and products. This must include designation of organizational responsibility and a schedule for the completion of the tasks and products identified in Section III. Applicants should also indicate the anticipated cost schedule per month for the entire project period.

F. Products

Applicants must concisely describe the interim and final products of each stage of the program, and must address the purpose, audience, and usefulness to the field of each product.

G. Program Budget

Applicants shall provide a 9-month budget with a detailed justification for all costs, including the basis for computation of these costs. Applicants should include a budget estimate to complete the balance of the program. Applications submitted by co-applicants and/or those containing contract(s) must include detailed budgets for each organization's expenses. The budget should include funds for a three-person Program Advisory Committee to meet twice during the 9-month budget period.

VII. Procedures and Criteria for Selection

All applications will be evaluated and rated based on the extent to which they meet the following weighted criteria. In general, all applications received will be reviewed in terms of their responsiveness to the minimum program application requirements, organizational capability, and thoroughness and innovativeness in responding to strategic issues in project implementation. Applications will be

evaluated by a peer review panel according to the OJJDP Competition and Peer Review Policy, 28 CFR Part 34, Subpart B, published August 2, 1985, at 50 FR 31366–31367. The selection criteria and their point values (weights) are as follows:

A. Organizational Capability (20 Points)

1. The extent and quality of organizational experience in the development, delivery and coordination of research programs that have been national in scope. (10 points)

2. Adequate fiscal controls and accounting procedures to ensure that the applicant can effectively implement a project of this size and scope, and to ensure the proper disbursal and accounting of Federal funds. (10 points)

B. Soundness of the Proposed Strategy (30 points)

Appropriateness and technical adequacy of the approach to each stage of the program for meeting the goals and objectives; and potential utility of proposed products.

C. Qualifiations of Project Staff (20 points)

1. The qualifications of staff identified to manage and implement the program including staff to be hired through contracts. (10 points)

2. The clarity and appropriateness of position descriptions, required qualifications and selection criteria relative to the specific functions set out in the Implementation Plan. (10 points)

D. Clarity and Appropriateness of the Program Implementation Plan (15 Points)

Adequacy and appropriateness of the activities, and the project management structure; and the feasibility of the time-task plan.

E. Budget (15 Points)

Completeness, reasonable, appropriateness and cost-effectiveness of the proposed costs, in relationship to the proposed strategy and tasks to be accomplished.

Applications will be evaluated by a peer review panel. The results of peer review will be a relative aggregate ranking of applications in the form of "Summary of Ratings." These will ordinarily be based on numerical values assigned by individual peer reviewers. Peer review recommendations, in conjunction with the results of internal review and any necessary supplementary reviews, will assist the Administrator in considering competing applications and in selection of the application for funding. The final award decision will be made by the OJJDP Administrator.

VIII. Deadline for Receipt of Applications

Applicants must submit the original signed application and three copies of OJJDP. The necessary forms for applications (Standard Form 424) will be provided upon request.

Applications must be received by mail or hand delivered to the OJJDP by 5:00 p.m. e.s.t. on July 27, 1988. Those applications sent by mail should be addressed to: NIJJDP/OJJDP, U.S. Department of Justice, 633 Indiana Avenue NW., Washington, DC 20531. Hand delivered applications must be taken to the NIJJDP, Room 784, 633 Indiana Avenue NW., Washington, DC, between the hours of 8:00 a.m. and 5:00 p.m. except Saturdays, Sundays or Federal holidays.

The NIJJDP/OJJDP will notify applicants in writing of the receipt of their application. Subsequently, applicants will be notified by letter as to the decision made regarding whether or not their submission will be recommended for funding.

IX. Civil Rights Compliance

A. All recipients of OJJDP assistant including any contractors, must comply with the non-discrimination requirements of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended; Title VI of the Civil Rights Act of 1964; Section 504 of the Rehabilitation Act of 1973 as amended; Title IX of the Education Amendments of 1972; the Age Discrimination Act of 1975; and the Department of Justice Non-Discrimination Regulations (28 CFR Part 42, Subparts C, D, E, and G).

B. In the event a Federal or State court or Federal or State administrative agency makes a finding of discrimination after a due process hearing on the grounds of race, color, religion, national origin or sex against a recipient of funds, the recipient will forward a copy of the finding to the Office of Civil Rights Compliance (OCRC) of the Office of Justice Programs.

C. Applicants shall maintain such records and submit to the OJJDP upon request timely, complete and accurate data establishing the fact that no person or persons will be or have been denied or prohibited from participation in benefits of, or denied or prohibited from obtaining employment in connection with, any program activity funded in whole or in part with funds made available under this program because of their race, national origin, sex, religion, handicap or age. In the case of any program under which a primary financial assistance to any other recipient of Federal funds extends financial assistance to any other recipient or contracts with any other person(s) or group(s), such other recipient, person(s) or group(s) shall also submit such compliance reports to the primary recipient as may be necessasry to enable the primary recipient to assure its civil rights compliance obligations under any award.

X. References

Agopian, M. (1981). Parental Child Stealing. Lexington, MA: *Lexington Books.*

Hotaling, G.T. and Finkelhor, D. (1985). The Sexual Exploitation of Missing Children: A Research Review, Prepared for the Office of Juvenile Justice and Delinquency Prevention, Department of Justice.

Terr, L. (1981). Psychic Trauma in Children: Observations following the Chowchilla School Bus Kidnapping, *American Journal of Psychiatry,* Vol. 138(1), 14–19.

Terr, L. (1983). Chowchilla Revisited: The Effects of Psychic Trauma Four Years After a School Bus Kidnapping, *American Journal of Psychiatry,* Vol. 53(2), 244–260.

Approved:

Date: June 15, 1988.

Verne L. Speirs,

Administrator, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 88–13853 Filed 6–17–88; 8:45 am]

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Federal Register

Monday
June 20, 1988

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Ch. I

Pediatric Dosing Information for Over-the-Counter Human Drugs; Intent and Request for Information; Notice of Intent

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 88N-0004]

Pediatric Dosing Information for Over-the-Counter Human Drugs; Intent and Request for Information

AGENCY: Food and Drug Administration.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is considering proposing a rule concerning dosing information in the labeling of over-the-counter (OTC) drug products for children under 12 years of age. The agency is considering this action because of advisory review panel recommendations, agency proposals, and comments that have been submitted to other rulemakings as part of the ongoing review of OTC drug products conducted by FDA. The agency is not proposing any regulatory changes in this notice. The purpose of this notice is to present a number of matters that the agency would like interested persons to address and to give interested persons an opportunity to (1) submit comments on how pediatric dosing information should be presented in the labeling of OTC drug products, and (2) present information and data on related issues and problems.

DATES: Written comments by October 18, 1988, and reply comments by November 17, 1988.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gibertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the course of FDA's OTC drug review, the advisory review panels that evaluated the safety and effectiveness of OTC drug products and the agency have given particular consideration to appropriate labeling and dosage directions for children. This document discusses the panels' recommendations concerning pediatric dosing information, the agency's proposed pediatric dosage labeling, and comments submitted in response to the panels' recommendatons and agency proposals.

The "OTC Volumes" cited in this document are on public display in the Dockets Management Branch.

I. Advisory Review Panel Recommendations Concerning Pediatric Dosages and the Agency's Adoption of These Recommendations

The advisory review panels varied in their recommendations concerning pediatric dosages for OTC drug products intended for systemic absorption as follows: The basis for their recommendations, the age ranges recommended, and the relationship between children's dosage levels and adult dosage levels. In general, the agency has accepted the panels' recommendations concerning pediatric dosing information and adopted labeling based on these recommendations in tentative final and final monographs for OTC drug products. The following are examples of the various recommendations.

A. Internal Analgesic OTC Drug Products

The Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products (Internal Analgesic Panel) reviewed the pediatric dosages in the labeling of internal analgesic/antipyretic drug products that were submitted to it (42 FR 35346; July 8, 1977) and noted the absence of a "recognized" pediatric dosage schedule for internal analgesic drug products (42 FR 35366). Data and information submitted to the Panel indicated that the pediatric dosages described in the labeling submitted to it provided children's dosage levels that are too low to be effective (Refs. 1 and 2). The Panel also reviewed the medical literature and standard references such as "AMA Drug Evaluations" (Ref. 3) and the "United States Pharmacopeia 19th Revision" (Ref. 4) to ascertain a basis for appropriate pediatric dosages for internal analgesic drug products (42 FR 35367). In determining the appropriate basis for pediatric dosages, the Panel discussed both the relationship between a child's body surface area and age and between a child's body weight and age (42 FR 35367 and 35368). Because the relationship between body surface area and age for children from ages 3 to 12 years is linear, and the relationship between body weight and age for children in this age group is nonlinear after the age of 7 years, the Panel based its pediatric dosage recommendations for internal analgesics upon the 1.5 grams/meter^2 body surface area daily dosage for that age as described by Done (Ref. 5).

For aspirin and acetaminophen, the Panel recommended a standard adult dosage unit of 325 milligrams (mg) and a standard pediatric dosage unit of 80 mg. Based on these dosage units, the Panel recommended the following pediatric dosages for aspirin and acetaminophen to be given every 4 hours up to five times a day while symptoms or fever persists, or as directed by a physician:

PANEL'S RECOMMENDED DIRECTIONS FOR PEDIATRIC DOSAGES OF ASPIRIN AND ACETAMINOPHEN

Age (years)	Pediatric (80-mg) dosage units		Adult (325-mg) dosage units	
	Number dosage units	Dosage in mg	Number dosage units	Dosage in mg
Under 2	(1)	(1)	(1)	(1)
2 to under 4	2	160	½	162.5
4 to under 6	3	240	¾	243.8
6 to under 9	4	320	1	325.0
9 to under 11	5	400	1¼	406.3
11 to under 12	6	480	1½	487.5

[1] Consult a doctor.

The agency plans to accept, with minor modifications, the Internal Analgesic Panel's recommended dosages for children for aspirin and acetaminophen in the proposed rule for OTC internal analgesic drug products, to be published in a future issue of the **Federal Register.** The agency plans to propose the following directions for pediatric dosages of acetaminophen, aspirin, and sodium salicylate:

AGENCY'S PROPOSED DIRECTIONS FOR PEDIATRIC DOSAGES OF ACETAMINOPHEN, ASPIRIN, AND SODIUM SALICYLATE

Age (years)	Number of 80-mg or 81-mg [1] dosage units	Number of 325-mg [1] dosage units
Under 2	Consult a doctor	Consult a doctor.
2 to under 4.	2	½.
4 to under 6.	3	¾.
6 to under 9.	4	1.
9 to under 11.	4 to 5	1 to 1¼.
11 to under 12.	4 to 6	1 to 1½.

[1] Dose may be repeated every 4 hours while symptoms persist, up to five times a day or as directed by a doctor.

References

(1) OTC Volume 030142, Docket No. 77N-0094, Dockets Management Branch.

(2) Clayton, J., *in* "Transcripts of Proceedings, Internal Analgesic Panel," pp. 1–8, April 9, 1976, Dockets Management Branch.
(3) "AMA Drug Evaluations," 2d Ed., American Medical Association, Chicago, pp. 264–265, 1973.
(4) "The Pharmacopeia of the United States of America," 19th Revision, The United States Pharmacopeial Convention, Inc., Rockville, MD, 1975.
(5) Done, A.K., *in* "Proceedings of the Conference on Effects of Chronic Salicylate Administration," edited by R.M. Lamont-Havers and B.W. Wagner, U.S. Government Printing Office, Washington, 1966.

B. Antiemetic OTC Drug Products

The Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (Laxative Panel) made recommendations concerning pediatric dosages for these classes of drug products, but did not specifically discuss the basis for its recommendations (40 FR 12902; March 21, 1975). The Panel made the following dosage recommendations for antiemetic drug products:

Cyclizine hydrochloride. The oral dosage for children 6 to 12 years of age is 25 mg up to three times daily. The oral dosage for adults is 50 to 200 mg daily.

Dimenhydrinate. The oral dosage for children 2 to 6 years of age is 12.5 to 25 mg up to three times daily and the oral dosage for children 6 to under 12 years of age is 25 mg up to three times daily. The adult oral dosage is 200 to 400 mg daily in four divided doses.

Meclizine hydrochloride. No oral dosage for children was recommended. The oral dosage for adults is 25 to 50 mg once daily.

In the final rule for OTC antiemetic drug products (52 FR 15886; April 30, 1987), the agency established dosages for the monograph ingredients that, except for dimenhydrinate, are consistent with the dosages recommended by the Laxative Panel. The agency added dosages for diphenhydramine hydrochloride and established the following dosages for OTC antiemetic drug products in the monograph:

(1) *For products containing cyclizine hydrochloride.* Adult oral dosage is 50 mg every 4 to 6 hours, not to exceed 200 mg in 24 hours or as directed by a doctor. For children 6 to under 12 years of age, the oral dosage is 25 mg every 6 to 8 hours, not to exceed 75 mg in 24 hours or as directed by a doctor.

(2) *For products containing dimenhydrinate.* Adult oral dosage is 50 to 100 mg every 4 to 6 hours, not to exceed 400 mg in 24 hours or as directed by a doctor. For children 6 to under 12 years of age, the oral dosage is 25 to 50 mg every 6 to 8 hours, not to exceed 150 mg in 24 hours or as directed by a doctor. For children 2 to under 6 years of age, the oral dosage is 12.5 to 25 mg every 6 to 8 hours, not to exceed 75 mg in 24 hours or as directed by a doctor.

(3) *For products containing diphenhydramine hydrochloride.* Adult oral dosage is 25 to 50 mg every 4 to 6 hours, not to exceed 300 mg in 24 hours or as directed by a doctor. For children 6 to under 12 years of age, the oral dosage is 12.5 to 25 mg every 4 to 6 hours, not to exceed 150 mg in 24 hours or as directed by a doctor.

(4) *For products containing meclizine hydrochloride.* No oral dosage for children was recommended. The oral dosage for adults is 25 to 50 mg once daily or as directed by a doctor.

C. Miscellaneous Internal OTC Drug Products

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products (Miscellaneous Internal Panel) provided pediatric dosage recommendations for anthelmintic drug products (45 FR 59540; September 9, 1980). Although the Panel did not discuss the basis for pediatric dosages for this class of drugs, it stated that OTC pinworm medication is not recommended for infants and children under 2 years of age or weighing less than 25 pounds (lb), except under the supervision of a physician. The Panel recommended weight-based dosages for pinworm active ingredients for both adults and children over 2 years of age.

In the final rule for OTC anthelmintic drug products (51 FR 27756; August 1, 1986), the agency adopted the Miscellaneous Internal Panel's dosage recommendations for the treatment of pinworm infestation with the active ingredient pyrantel pamoate, i.e., for adults (over 12 years) and children 2 to under 12 years of age, the oral dosage is a single dose of 5 mg per lb or 11 mg per kilogram (kg) of body weight not to exceed 1 gram (g). The agency also included in the monograph the following table that specifies dosages in mg for specified body weight ranges:

DIRECTIONS FOR DOSAGES OF ANTHELMINTIC DRUG PRODUCTS BASED ON WEIGHT

Weight	Dosage (taken as a single dose)[1]
Less than 25 pounds or under 2 years old.	Do not use unless directed by a doctor.
25 to 37 pounds..	125 milligrams.
38 to 62 pounds..	250 milligrams.
63 to 87 pounds..	375 milligrams.
88 to 112 pounds.	500 milligrams.
113 to 137 pounds.	625 milligrams.
138 to 162 pounds.	750 milligrams.
163 to 187 pounds.	875 milligrams.
188 pounds and over.	1,000 miligrams.

[1] Depending on the product, the label should state the quantity of drug as a liquid measurement (e.g., teaspoonsful) or as the number of dosage units (e.g., tablets) to be taken for the varying body weights. (If appropriate, it is recommended that a measuring cup graduated by body weight and/or liquid measurement be provided with the product.) Manufacturers should present this information as appropriate for their product and may vary the format of this chart as necessary.

D. Cough-Cold OTC Drug Products

The Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (Cough-Cold Panel) recommended children's dosage directions for many OTC cough-cold active ingredients (41 FR 38312; September 9, 1976). That Panel, stating that it was aware that data on the use in children of most cough-cold drug products was negligible or nonexistent, acknowledged that cough-cold drug products are widely used in the pediatric patient population (41 FR 38333). The Panel stated that optimum dosages of a drug in adults and children are dependent on factors such as the drug itself; individual patient variables such as special sensitivity or tolerance to the specific drug; the age and weight of the patient; and metabolic, pathologic, or psychological conditions in the patient. The Panel believed that, ideally, pediatric dosages should be derived from clinical trials with children, but recognized the extreme difficulties attendant upon such trials. The Panel stated that, traditionally, pediatric dosage calculations for infants and children have been based on body surface area, weight, or age of the child as a proportion of the "usual adult dose." The Panel recognized that determining children's dosages based on age, although convenient, may be the least reliable method because of the large variation in weight of patients at a specific age. However, the Panel stated that OTC drug products have a wide margin of safety and recommended that children's dosages be based on age. The Panel sought the assistance of a panel of experts in pediatric drug therapy (41 FR 38333) in establishing appropriate children's dosages for OTC cough-cold

drug products. Based on the recommendation of that panel of experts, the Panel recommended that for infants under 2 years of age, the pediatric dosage should be established by a physician; for children 2 to under 6 years of age, the dosage be one-fourth the adult dosage; and for children 6 to under 12 years of age, the dosage be one-half the adult dosage. Accordingly, the recommended dosages for children for the active ingredients included in the Panels recommended monograph were based on these dosage guidelines.

Although the Cough-Cold Panel recommended OTC pediatric dosages for children 2 to under 6 years of age for antitussive, 'bronchodilator, expectorant, and nasal decongestant drug products, it recommended that dosages for children in this age group for antihistamine drug products be placed in the professional labeling section of the monograph, i.e., for use only under the advice and supervision of a physician.

In general, the agency adopted the Cough-Cold Panel's recommended dosages for children in proposed rules for OTC antihistamine drug products (50 FR 2200; January 15, 1985 and 52 FR 31892; August 24, 1987), OTC nasal decongestant drug products (50 FR 2220; January 15, 1985), and OTC antitussive drug products (48 FR 48576; October 19, 1983), and in the final rule for OTC antitussive drug products (52 FR 30042; August 12, 1987).

In the proposed rule for OTC antihistamine drug products (50 FR 2200 and 52 FR 31892), the agency established that the OTC dosages for all Category I active ingredients for children 6 to under 12 years of age is one-half the adult dose. In addition, the agency concurred with the Panel and proposed in the tentative final monograph that pediatric dosages for children 2 to under 6 years be placed in the professional labeling section of the monograph (50 FR 2217 and 52 FR 31914). For one drug, chlorcyclizine, the professional labeling included the dosages for both children 6 to under 12 years of age and 2 to under 6 years of age. The professional labeling dosages for all Category I active ingredients, with the exception of triprolidine hydrochloride, for children 2 to under 6 years of age is one-fourth the adult dose. The proposed professional labeling dosages for triprolidine hydrochloride are an oral dose of 0.938 mg every 4 to 6 hours, not to exceed 3.744 mg in 24 hours, for children 4 to under 6 years of age (approximately 37.5 percent of the adult dose); an oral dose of 0.625 mg every 4 to 6 hours, not to exceed 2.5 mg in 24 hours, for children 2 to under 4 years of age (25 percent of the adult dose); and an oral dose of 0.313 mg every 4 to 6 hours, not to exceed 1.252 mg in 24 hours, for infants 4 months to under 2 years of age (12.5 percent of the adult dose) (52 FR 31914).

In the proposed rule for OTC nasal decongestant drug products (50 FR 2220), the agency's proposed OTC dosages for all Category I oral active ingredients for children 6 to under 12 years of age are one-half the adult dose and for children 2 to under 6 years of age are one-fourth the adult dose.

In the final rule for OTC antitussive drug products (52 FR 30042), the agency's established OTC dosages for all monograph oral active ingredients for children 6 to under 12 years of age are one-half the adult dose. The OTC dosages for all Category I active ingredients, except chlophedianol hydrochloride and codeine preparations, for children 2 to under 6 years of age is one-fourth the adult dose. The dosage for chlophedianol hydrochloride for children 2 to under 6 years of age is one-half rather than one-fourth the adult dose and is restricted to use under the supervision of a physician (i.e., is included in the professional labeling section of the monograph). Dosages for codeine preparations for children 2 to under 6 years of age are also restricted to use under the supervision of a physician and are included under the professional labeling section of the monograph. The following dosages for codeine preparations for children 2 to under 6 years of age are weight-based and a calibrated measuring device is required for use in children in this age group:

For products containing codeine ingredients identified in § 341.14(a)(2). (1) Children 2 to under 6 years of age: Oral dosage is 1 mg per kg body weight per day administered in four equal divided doses. The average body weight for each age may also be used to determine dosage as follows: for children 2 years of age (average body weight, 12 kg), the oral dosage is 3 mg every 4 to 6 hours, not to exceed 12 mg in 24 hours; for children 3 years of age (average body weight, 14 kg), the oral dosage is 3.5 mg every 4 to 6 hours, not to exceed 14 mg in 24 hours; for children 4 years of age (average body weight, 16 kg), the oral dosage is 4 mg every 4 to 6 hours, not to exceed 16 mg in 24 hours; for children 5 years of age (average body weight, 18 kg), the oral dosage is 4.5 mg every 4 to 6 hours, not to exceed 18 mg in 24 hours. The manufacturer must relate these dosages for its specific product to the use of the calibrated measuring device discussed in paragraph (3) of this section. If age is used to determine the dose, the directions must include instructions to reduce the dose for low-weight children.

(2) Parents should be instructed to obtain and use a calibrated measuring device for administering the drug to the child, to use extreme care in measuring the dosage, and not exceed the recommended daily dosage.

(3) A dispensing device (such as a dropper calibrated for age or weight) should be dispensed along with the product when it is intended for use in children 2 to under 6 years of age to prevent possible overdose due to improper measuring of the dose.

(4) Codeine is not recommended for use in children under 2 years of age. Children under 2 years may be more susceptible to the respiratory depressant effects of codeine, including respiratory arrest, coma, and death.

II. Comments on Pediatric Dosing Information

In response to the pediatric dosage recommendations of the Cough-Cold Panel and the agency's proposals concerning the Panel's recommendations for antihistamine, antitussive, and nasal decongestant drug products, the agency has received comments from four manufacturers and one manufacturers' association requesting that the pediatric dosages for cough-cold drug products be revised to provide a greater subdivision of age ranges for children under 12 years of age that would more closely approximate weight-based dosages. The comments' revised dosages are based on a standardized pediatric dosing unit and standardized dosing age ranges (as described below) for the drugs in these categories. Copies of these comments are on public display in the Dockets Management Branch (Ref. 1). The agency notes that similar requests for this pediatric dosage revision have not been received in other OTC drug rulemakings to date.

In response to the tentative final monograph for OTC antihistamine drug products (50 FR 2200 and 52 FR 31892), the agency has received comments from one manufacturer and one manufacturers' association requesting that the pediatric dosages for children 2 to under 6 years of age for antihistamine drug products be included in the OTC labeling directions in the monograph. Copies of these comments are on public display in the Dockets Management Branch (Ref. 2).

References

(1) Comment Nos. C00197, C00200, C00201, C00204, C00206, C00207, C00208, C00209, C00210, C00211, CR0005, CR0006, in OTC Volume 00PDNI, Docket No. 88N–0004, Dockets Management Branch.

(2) Comment Nos. C00210 and C00211 in OTC Volume 00PDNI, Docket No. 88N–0004, Dockets Management Branch.

A. Standardized Pediatric Dosage Units

In general, the comments stated that it is important to achieve a consistent approach to pediatric dosing of OTC drug products in the marketplace and in the agency's rulemakings and that the dosage schedules should provide (1) relatively fixed dosage forms, (2) sufficient flexibility in the dosage schedules by basing the schedules on weight and age, (3) the ability to correlate dosing with a greater subdivision of standard age breaks, and (4) ease of physician and consumer use. The comments pointed out that there are significant differences between the pediatric dosing schedules recommended by the Internal Analgesic Panel for internal analgesic drug products (42 FR 35346) and the agency's pediatric dosing schedules for cough-cold drug products such as antihistamines and nasal decongestants. The comments explained that the agency's children's dosages for OTC antihistamine, antitussive, and nasal decongestant drug products provide only two age ranges for children under 12 years of age (6 to under 12 years and 2 to under 6 years, with professional labeling only for the use of antihistamines in the under 6 age group) whereas the Panel's recommendations for the children's dosages for internal analgesics provided the following five age ranges with shorter age spans for children under 12 years of age: 11 to under 12 years, 9 to under 11 years, 6 to under 9 years, 4 to under 6 years, and 2 to under 4 years. According to the comments, the pediatric dosage schedule for internal analgesics is better than the dosage schedules for cough-cold drug products because the internal analgesic dosage schedule correlates more closely with the practice of basing children's dosages to body weight. The comments stated that the use of body weight is widely accepted by pediatricians as a preferred method of determining drug dosages for children. In addition, it is well recognized that variations in weight have a significant impact on appropriate dosage levels for different individuals, and that body weight varies significantly with age for children between the ages of 2 and 12 years because this is a period of rapid growth. Therefore, it is appropriate to have a greater subdivision of age ranges in the recommended dosages for the 2- to 12-year age group so that the dosages correspond better to body weight variations due to rapid growth.

The comments recommended that a standard pediatric dosing unit be established based on both weight and age considerations and suggested that a good standard pediatrric dosing unit would be one-eighth of the adult dose. This standard pediatric dosing unit would correlate with 6-lb increments as a child grows and could be used with the 50th percentile weights for age ranges to produce the following dosing increments for the given age and weight ranges (Ref. 1):

COMMENTS' SUGGESTED STANDARDIZED PEDIATRIC DOSING SCHEDULE

Age (years)	Weight (lb)	Appropriate number of dosing units [1]
4 months to under 1	12 to 17	1
1 to under 2	18 to 23	1.5
2 to under 4	24 to 35	2
4 to under 6	36 to 47	3
6 to under 9	48 to 59	4
9 to under 11	60 to 71	5
11 to under 12	72 to 95	6
12 and over	96 and over	8

[1] 1 dosing unit equals one-eighth adult dose.

The comments pointed out that applying the above dosing schedule to OTC drug products would not result in doses that exceed the currently proposed doses for internal analgesics where toxicity is a real concern, and yet would prevent underdosing of older children at the top end of the cough-cold dosing age range of 6 to under 12 years.

One comment requested that the directions for use for OTC oral antitussive drug products proposed in the tentative final monograph be modified to improve the OTC dosage schedules for children 2 to 12 years of age. The comment specifically addressed the agency's proposed dosage schedule in § 341.74(d)(1)(iv) for dextromethorphan and dextromethorphan hydrobromide (48 FR 48594) and recommended that the dosage schedules for children under the age of 12 have a greater subdivision of age ranges than the dosage schedules proposed in the tentative final monograph. For children under 12 years, the comment recommended eight weight-based and age-related dosage ranges, with both age and weight ranges specified in the labeling, to replace the agency's two proposed age-based ranges in the dosage schedule for dextromethorphan. The comment submitted a report and literature references in support of a safe and effective dose range of 0.3 to 0.5 mg/kg for dextromethorphan and in support of weight-based, age-related dosage schedules for children under 12 years of age in general (Ref. 2).

The comment contended that its recommended dosage schedule provides improvements over the agency's proposed dosage schedule in that it provides more age subdivisions for children under 12 years of age to assure more consistent dosage in a particular dosage range, and it provides a weight-based dosage schedule for children 2 to under 12 years of age that supplements the age-based dosage schedule.

In 1986, the American Academy of Pediatrics considered the dosing recommendations in the tentative final monographs for OTC antihistamine, antitussive, and nasal decongestant drug products and encouraged the agency to accept the comments' recommendations to adopt the more weight-based, age-related dosage ranges for children's dosages of OTC drug products (Ref. 3).

References

(1) Minutes of Meeting, dated February 25, 1985, "Changing Children's Dosage Schedules for OTC Antihistamine and Nasal Decongestant Drug Products to Provide More Age Intervals, to Add Weight-Based Dosages, and to Extend OTC Package Labeling Dosage Schedules for Antihistamines Down to 2 Years of Age," identified as MM00002, Docket No. 76N–052H, Dockets Management Branch.

(2) Comment Nos. C00197 and CR0005, Docket No. 76N–052T, Dockets Management Branch.

(3) Letters from R.J. Roberts, Chairman, Committee on Drugs, American Academy of Pediatrics, to W.E. Gilbertson, FDA, OTC Volume 00PDNI, Docket No. 88N–0004, Dockets Management Branch.

1. *Weight ranges in OTC pediatric labeling.* The comments also recommended that OTC drug labeling should consider the needs of children who are in the 10th or 90th percentile ranges for weight by including weight ranges in addition to age ranges for dosing. One comment requested that manufacturers be permitted to include pediatric dosages based on weight in the labeling of OTC drug products because it is a medically sound alternative. Several comments stated that an additional benefit of optionally available weight-related dosages is that they can be used when a child's weight is known, especially for children that are very large or very small for their age or when children approach the usual age breaks for a given dosing schedule. The comments explained further that dosing

for drugs in the pediatric patient has been recommended on the basis of age, weight, and body surface area; however, there are specific advantages to each of these approaches to determine the proper dose for a pediatric patient. While body surface area may be the most accurate parameter to use in determining the proper dose for a child, body surface area is not a parameter that is commonly used by pediatricians and it is clearly not a parameter that is used by parents. Because changes in weight are reasonably similar to changes in body surface area and the weight of a child is more likely to be known to a pediatrician or a parent than body surface area, dosing based on weight is a reasonable substitute for dosing based on body surface area. However, a child's weight is not always known at the time that a physician recommends a dosage or at the time that a parent is determining the proper dose for a child. Because the age of a child is almost always know, it is the simplest parameter for consumer use in determining the appropriate dose for a child. The comments stated that age can be used as a reasonable guide to growth in the child provided that the wide variations in growth that occur in children are taken into consideration. The comments concluded that weight-based dosages offer a significant benefit for those consumers or health professionals who would like to dose by weight, but that weight-based dosages should be optional in labeling because weight is not always known. The comments also stated that, in order to avoid unnecessary consumer and health professional confusion when such weight-based dosages are made available, all pediatric product labeling that provides weight-based dosages should use the standardized weight schedule provided in the table above.

2. *Standardized pediatric dosages as optional labeling.* Several comments recommended that the pediatric dosage labeling based on more finely subdivided age ranges be optional. One comment requested that this dosage labeling be optional and that it be added to the current dosages in the tentative final monographs to accommodate products intended primarily for pediatric populations. Other comments stated that for those products targeted toward adults, which also provide dosage recommendations for the pediatric patient, it is reasonable to continue to allow the option of using dosages proposed in the tentative final monographs, i.e., dosages for the age ranges 2 to under 6 years and 6 to under 12 years. Other comments did not request that the pediatric dosage labeling based on more finely subdivided age ranges be optional.

3. *Professional labeling for children under 2 years.* Two comments from the same manufacturer recommended that dosages based on the standardized pediatric dosage unit for children under 2 years of age be added to the professional labeling sections of the nasal decongestant and antihistamine monographs. The comments recommended that dosages for nasal decongestant and antihistamine drug products should be as follows: for children 1 year of age, one and one-half times the standardized pediatric dosage unit (one pediatric dosage unit equals one-eighth the adult dose) and for children 4 to 11 months, one standardized pediatric dosage unit. One of the comments provided specific dosages for children 4 and under 24 months of age based on the above standardized pediatric dosage units for the active ingredients acetaminophen, chlorpheniramine, destromethorphan, and pseudoephedrine (Ref. 1). Another comment from the same manufacturer recommended that the following dosages for dextromethorphan based on weight and age for children under 2 years of age be added to the professional labeling sector of the antitussive monograph:

COMMENT'S SUGGESTED PEDIATRIC DOSING SCHEDULE FOR DEXTROMETHORPHAN

Weight		Age (months)	Dextromethorphan	
(kg)	(lb)		Dose every 4–6 hours (mg)	Dosing range (mg/kg)
2.5–5.4	6–11	Under 4	1.25	0.23–0.50
5.5–7.9	12–17	4–11	2.5	0.32–0.45
8.0–10.9	18–23	12–23	3.75	0.34–0.47

Reference

(1) Comment No. C00211, Docket No. 76N–052H, Dockets Management Branch.

4. *Pediatric dosage labeling for OTC cough-cold combination drug products.* Several comments noted that OTC antihistamines, antitussives, nasal decongestants, and internal analgesics are often combined. In order to allow for combination drug products to be labeled with consistent pediatric dosage information, these comments requested that the agency adopt children's dosages for antihistamines, antitussives, and nasal decongestants that are similar to and consistent with the pediatric dosages for internal analgesics. One comment stated that, for products primarily intended for pediatric use, revised cough-cold pediatric dosages similar to those for analgesic/antipyretic dosages would provide consistency among various monographs and allow for consistency in the formulation of combination drug products.

Another comment from a manufacturer stated that the dosages for children 6 to under 12 years of age proposed in the antihistamine tentative final monograph (§ 341.72(d); 50 FR 2216 to 2217) cannot be reconciled with the dosage recommendations of the Internal Analgesic Panel (Pediatric Schedule C; 42 FR 35368). The comment stated further that the combination of a Category I antihistamine and a Category I analgesic/antipyretic has been recommended by both the Cough-Cold Panel (41 FR 38326) and the Internal Analgesic Panel (42 FR 35370). Thus, the comment contended, the 6- to under 12-year age group should not be deprived of the benefit of such a combination drug product. The comment recommended specific pediatric dosages for chlorpheniramine that are consistent with the dosages for analgesic/antipyretic ingredients and that would allow pediatric combination drug products containing these ingredients. The comment contended that no significant safety issue would be involved in allowing such combinations.

Another comment from the same manufacturer stated that there is a need to harmonize the dosage regimens of cough-cold ingredients and internal analgesic/antipyretic ingredients for pediatric use and that failure to provide for consistency in these pediatric dosages for cough-cold and analgesic/antipyretic drug products would result in the removal from the market of combination drug products intended for use in children under 12 years of age. However, the comment did not provide any examples of specific products that would be removed from the market. The comment stated that the agency should not ignore the reality that nasal congestion frequently occurs concurrently with fever and/or pain in children as well as adults. Further, for concurrent symptoms, the administration of few rather than many dosage units to children will meet with less resistance, thereby increasing patient compliance and benefit. The comment provided several examples of the problems that would arise in providing appropriate pediatric dosages for combination drug products containing oral nasal decongestants and analgesics/antipyretics because of the inconsistencies in the dosage

recommendations for these classes of drugs (Ref. 1). The comment stated that these examples emphasize the need for intermonograph consistency for pediatric dosages and that the alternative to consistency among monograph dosages would be a plethora of dosage forms or label directions which would only confuse the consumer needlessly.

Another comment pointed out that although the Internal Analgesic Panel recognized that antitussive/analgesic combination drug products are rational therapy for concurrent symptoms (42 FR 35493), the dosage range proposed by the agency in § 341.74(d)(1)(iv) for dextromethorphan for children 2 to under 12 years of age (48 FR 48594) is incompatible with the pediatric dosage schedule proposed by the Internal Analgesic Panel for aspirin or acetaminophen. The comment argued that the Internal Analgesic Panel's recommended limitation of the maximum daily pediatric doses of aspirin of acetaminophen to no more than five daily doses would preclude a combination drug product containing an internal analgesic ingredient and an antitussive ingredient from providing the maximum permitted daily dose of dextromethorphan, and thereby deprive the child of maximum antitussive benefit. The comment presented the following example: a liquid antitussive/analgesic drug product for use by children 2 to under 11 years of age could be given no more than five times a day thus delivering a maximum of 50 mg dextromethorphan. Because the permitted maximum daily dose of dextromethorphan is 60 mg, the child would be "deprived" of an additional 10 mg dextromethorphan.

The comment maintained that dextromethorphan has a wide margin of safety. Quoting the Cough-Cold Panel's report and the agency's tentative final monograph, the comment stated that "there have been no fatalities 'even with doses in excess of 100 times the normal adult dose' " (41 FR 38340) and "because of its low order of toxicity, dextromethorphan is probably the safest antitussive presently available," (48 FR 48581). The comment argued that it is both safe and sound therapy to permit the total daily amount of dextromethorphan proposed for children to be administered in five rather than six doses. Therefore, the comment urged that the limitations on the amount of dextromethorphan in a single dose be increased to permit the pediatric patient to obtain the maximum potential 24-hour benefit of the dextromethorphan.

Reference

(1) Comment No. C00200, Docket No. 76N-052N, Dockets Management Branch.

B. OTC Labeling of Antihistamine Drug Products for Children 2 to Under 6 Years of Age

One comment presented data from a survey of 200 pediatricians concerning these physicians' use of OTC cough-cold and internal analgesic drug products in children as well as their preferences for the pediatric labeling of these drug products (Ref. 1). When asked whether the pediatricians recommend the use of these products in children in the age ranges of 2 to 5 years and 6 to 14 years, over 90 percent said that they did recommend use in both age ranges with the exception of aspirin. Responses to how the pediatricians determine the dose of cough-cold or internal analgesic drugs for children varied widely from using the "Physician's Desk Reference" (PDR) or pediatric handbooks to personal experience in using the drugs in children. The comment pointed out that these wide variations in determining pediatric doses lead to inconsistent dosing of children. Although the proposed OTC drug labeling provides a basis for consistency in dosing for children 6 years of age and over, dosing for children under 6 years is less consistent if the OTC drug labeling, e.g., the proposed antihistamine labeling, does not provide dosages for children in this age group. The pediatricians were asked for their preferences in dosing parameters in the labeling of OTC drug products, i.e., age, weight, age *and* weight, body surface, or other parameter. The majority (61 to 63 percent) said that they would prefer age *and* weight dosing parameters in the OTC labeling of antihistamines, antitussives, nasal decongestants, and internal analgesics. The survey revealed that the majority (51 percent) of the pediatricians believe that pediatric dosing information for children under 2 years of age in OTC drug labeling would be "very beneficial" and an additional 34 percent believe such labeling would be "somewhat beneficial." In response to a question concerning the comfort level of including pediatric dosing information in OTC drug labeling, most pediatricians expressed a "high comfort level" with such labeling.

Reference

(1) Comment No. C00211, Docket No. 76N-052H, Dockets Management Branch.

III. Agency Response Regarding Changes in Pediatric Dosing Information for OTC Drug Products

After reviewing these comments and other pertinent information, the agency has determined that additional information is required before it will be able to ascertain whether changes are needed in the manner in which pediatric dosing information is presented in the labeling of OTC drug products. The agency is publishing this notice of intent and request for information to elicit further comments and/or data concerning pediatric dosages. The agency is inviting further public comment on the following matters concerning pediatric dosages: (1) Should the agency retain only its current general schedule for pediatric dosing information (i.e., ages 2 to under 6 and 6 to under 12) or expand this format, (2) if the answer is to expand, then how many additional age ranges should be included, and what should these age subdivisions be, (3) should a standard pediatric dosing schedule based on both weight and age be adopted, (4) if the answer is yes, how should this schedule be designated, (5) should this expanded pediatric dosage labeling be required for all OTC drug products or should it be optional, (6) what OTC drug products should this schedule apply to—both to class and dosage form, (7) if an expanded dosage schedule is adopted, are calibrated dosing devices necessary to ensure that the more finely subdivided dosages are accurately administered, and (8) is it safe to provide pediatric dosages for children 2 to under 6 years of age in the OTC labeling directions for antihistamine drug products?

In addressing these questions, consideration should be given to the following factors:

1. A number of comments presented good reasons why additional pediatric age subdivisions and/or weight-based, age-related dosages are scientifically and medically sound and would be beneficial in OTC drug labeling. However, some of these comments requested that such pediatric dosage labeling be optional and stated that it would be reasonable to allow products that are targeted primarily for adults, but that also provide pediatric dosage information in the labeling, to continue to use the pediatric dosage directions proposed in the tentative final monographs. The comments did not elaborate further as to why the requested changes in the pediatric dosage information should not be applicable to all products that contain

pediatric dosage labeling. The reasons for requesting that inconsistent pediatric dosage information be allowed for different types of cough-cold products is unclear. The agency questions why, if the greater subdivision of age ranges in the 2- to 12-year age group provides better dosing that corresponds to body weight variations, this dosing information should not appear on the labeling of all applicable OTC drug products.

2. The agency has received comments recommending revised pediatric dosages for only antihistamine, antitussive, and nasal decongestant drug products. These revised dosages are similar to the pediatric dosing concept that was proposed by the Internal Analgesic Panel for internal analgesic/antipyretic drug products. If the more detailed pediatric dosages are appropriate for the above categories of drugs, it would seem they should also apply to other types of OTC drug products, e.g., expectorants, systemic bronchodilators, antiemetics, and/or systemic laxatives. The basis for requesting more finely subdivided pediatric dosage age ranges for some cough-cold products is that dosages that correlate more closely with weight will provide better dosing of children during the rapid growth age range between 2 and 12 years of age. This reasoning would seem to apply to any systemic drug product. In order to provide consistency in the agency's approach to pediatric dosage directions, the agency would like to identify which drug classes should be affected by revised pediatric dosages and any information that would support a different approach for different drug classes that include systemic drug products. The agency also invites comment as to whether greater age/weight variations would be pertinent for topically applied OTC drugs.

3. The comments did not mention the use of calibrated dosing devices for liquid dosage forms in general to ensure that the requested dosages, which are more finely subdivided than the currently proposed doses, will be given to the child accurately. The agency requests comments as to whether it would be appropriate to direct parents to use calibrated measuring devices for liquid products to facilitate and ensure that the more finely divided doses are administered as accurately as possible when they are given to the child. The agency also invites comments concerning the manner in which solid dosage forms should be formulated to ensure accurate dosing of children, e.g., providing tablets that contain no more than one-eighth to one-fourth the adult dose.

4. For many years, the use of antihistamine drug products in children 2 to under 6 years of age has been restricted to use only under the supervision of a physician. The Cough-Cold Panel did not recommend that dosage labeling for this age group be included in the OTC labeling for antihistamine drug products. The Panel recommended that such labeling be placed in the professional labeling section of the monograph (41 FR 38312), and the agency agreed with the Panel's recommendations in the tentative final monograph (50 FR 2200 and 52 FR 31914). No data concerning the safety of OTC use of antihistamines in children 2 to under 6 years of age were submitted by comments that requested that dosages for this age group be included in the OTC labeling of these drug products. The agency believes that evaluation of information concerning the safety of antihistamine use in children 2 to under 6 years of age without the supervision of a physician is necessary before the agency can make a decision concerning the switch of dosage labeling for this age group for antihistamines from professional use only to OTC labeling for consumer use. The agency is particularly concerned with the safety of OTC use of the antihistamines diphenhydramine hydrochloride and doxylamine succinate in children 2 to under 6 years because these antihistamines produce more drowsiness and depress the central nervous system to a greater extent than other OTC antihistamine ingredients. The agency believes that the use of calibrated measuring devices for these antihistamine drug products in liquid dosage forms and the formulation of solid dosage forms to restrict the amount of ingredient per dosage unit may be necessary to ensure accurate administration of the dosages to children and to prevent possible toxicity in children 2 to under 6 years due to an overdose of an antihistamine drug product. The agency requests specific comment on this matter.

Decisions to revise pediatric dosage labeling in the absence of studies in children that support the safety and effectiveness of such dosage labeling are particularly difficult. The agency requests the submission of further data and information pertinent to the matters discussed above as well as the safety and effectiveness of the requested revised dosage levels for children under 12 years of age. The agency is not proposing any regulatory changes in this document. After the agency evaluates all of the comments, data, and information received, it will determine whether it should propose any regulatory changes in the manner in which pediatric dosing information is presented in the labeling of OTC drug products. Based on the comments, data, and information received, if the agency determines that information concerning the use of antihistamine drug products should appear in the OTC labeling, appropriate proposals to amend the monograph for OTC antihistamine drug products will be made in a future issue of the **Federal Register**.

Interested persons may, on or before October 18, 1988, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this notice of intent and request for information. Three copies of all 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 and may be accompanied by a supporting memorandum or brief. Comments replying to comments may also be submitted on or before November 17, 1988.

Comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 22, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88–13830 Filed 6–17–88; 8:45 am]

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Federal Register

Monday
June 20, 1988

Part V

Department of State

22 CFR Part 136

Personal Property Disposition at Posts Abroad; Interim Rule With Request for Comments

DEPARTMENT OF STATE

22 CFR Part 136

Personal Property Disposition at Posts Abroad

AGENCY: Department of State.

ACTION: Interim Rule with request for comments.

SUMMARY: This action promulgates an interim rule setting forth regulations governing disposition of personal property abroad by certain United States Government employees and contractors, and members of their families. Consistent with the intent of Congress, the purpose of these regulations is to ensure that employees and members of their families do not personally profit from transactions with persons not entitled to exemptions from import restrictions, duties, or taxes. *See* H. Conf. Rep. No. 100–475, 100th Cong., 1st sess. (Dec. 14, 1987), at 142.

DATES: Interim rule is effective June 20, 1988. Interested parties may file comments on this interim rule on or before August 20, 1988.

ADDRESS: Comments may be filed with the Office of the Comptroller, Department of State, Washington, DC 20520.

FOR FURTHER INFORMATION CONTACT: Mr. James Marable, Office of the Comptroller, telephone (703) 875–6918.

SUPPLEMENTARY INFORMATION: This interim final rule is published to implement Title III of the State Department Basic Authorities Act of 1956 ("the Act"), as enacted by section 186 of the Foreign Relations Authorization Act, Fiscal Years 1988 and 1989 (Pub. L. 100–204). The interim rule is made effective on June 20, 1988, the effective date of Title III, since in the absence of regulations all dispositions of personal property abroad by covered employees or members of their family would be prohibited by law.

The regulations set forth basic general requirements and procedures. Pursuant to section 303(c) of the Act, the regulations authorize the chief of mission in each foreign country to establish more detailed policies, rules or procedures for application of Title III of the Act in that country.

Section 301(6) of the Act authorizes the exclusion by regulation of items of "minimal value" from the definition of "personal property" subject to restrictions on disposition under the Act. In most countries, the opportunity to realize significant profits from the sale of duty-free of tax-free personal property is limited to high value items such as automobiles, computers, boats, and audio and video equipment. Consequently, these regulations generally define "minimal value" consistent with the determination of "minimal value" by the Administrator of General Services for foreign gift purposes, currently $180.

There are, however, a few countries where import restrictions, tax policies or other special conditions make it possible for persons possessing customs or tax exemptions to accrue substantial personal profits by reselling low value items such as used clothing. In addition to producing personal profits contrary to the intent of the Act, "garage sales" by employees in such countries may be a source of diplomatic embarrassment to the United States. Accordingly, these regulations provide that the chief of mission may control sales of low value items, either by setting a lower ceiling for the "minimal value" exclusion from restriction on sales, by restricting total proceeds or profits from sales of minimal value items, or by restricting the manner in which such goods are sold.

In addition to employees, the Act requires that provisions be placed in contracts to effect coverage of the disposition of personal property by contractors who enjoy importation or tax privileges in a foreign country because of their contractual relationship to the United States Government. These regulations set forth this requirement, which will be implemented as a matter of procurement regulation through a parallel rulemaking in the Federal Acquisition Regulation (48 CFR chapter 1).

Regulatory Flexibility Act

These regulations will not have a significant impact on a substantial number of small entities. They will affect principally Federal employees who enjoy customs or tax exemptions in a foreign country in connection with their employment by the United States Government.

Paperwork Reduction Act

These regulations do not require additional reporting under the criteria of the Paperwork Reduction Act of 1980.

Waiver of Notice of Proposed Rulemaking and 30-Day Delay of Effective Date.

To the extent that these rules or portions thereof are not exempt from the requirements of 5 U.S.C. 553 as relating to personnel, the Secretary of State has determined pursuant to 5 U.S.C. 553 (b)(B) and (d)(3) that good cause exists for waiving the general notice of proposed rulemaking and for making these regulations effective in less than 30 days. Absent effective regulations, all dispositions of personal property by USG employees and family members at posts abroad would be prohibited under the general rule of section 302(a) of the State Department Basic Authorities Act of 1956, as amended. Such a blanket prohibition on sales was not intended by the Congress, would work an undue hardship on covered employees and their families, and would cause the USG to incur transportation expenses in shipping household effects that would otherwise be sold at post.

List of Subjects in 22 CFR Part 136

Government employees, foreign relations.

Accordingly, new Part 136 is added to Title 22, Code of Federal Regulations, as follows:

PART 136—PERSONAL PROPERTY DISPOSITION AT POSTS ABROAD

Sec.

Authority: 22 U.S.C. 4341.

§ 136.1 Purpose.

The primary purpose of these regulations is to ensure that employees and members of their families do not profit personally from sales or other transactions with persons who are not themselves entitled to exemption from import restrictions, duties, or taxes.

§ 136.2 Authority.

Section 303(a) of the State Department Basic Authorities Act of 1956 authorizes the Secretary of State to issue regulations to carry out the purposes of Title III of that Act.

§ 136.3 Definitions.

(a) "Basis" of an item shall include the initial price paid (or retail value at the time of acquisition if acquired by gift), inland and overseas transportation costs (if not reimbursed by the United States Government), shipping insurance, taxes, customs fees, duties or other charges, and capital improvements, but shall not include insurance on an item while in use or storage, maintenance, repair or related costs, or financing charges.

(b) "Charitable contribution" means a contribution or gift as defined in section 170(c) of the Internal Revenue Code, or other similar contribution or gift to a bona fide charitable foreign entity as

determined pursuant to policies, rules or procedures issued by the chief of mission pursuant to 136.5(b).

(c) "Chief of mission" has the meaning given such term by section 102(e) of the Foreign Service Act of 1980 (22 U.S.C. 2902(3).

(d) "Contractor" means: (1) An individual employed by personal services contract pursuant to section 2(c) of the State Department Basic Authorities Act of 1956 (22 U.S.C. 2669(c)), pursuant to section 636(a)(3) of the Foreign Assistance Act of 1961 (22 U.S.C. 2396(a)(3)), or pursuant to any other similar authority including, in the case of an organization performing services under such authority, an individual involved in the performance of such services; and (2) any other individual or firm that enjoys exemptions from import limitations, customs duties or taxes on personal property from a foreign country in connection with performance of a contract for goods or services when such contract is with the United States Government or an agency or instrumentality thereof or when such contract is directly financed by grant assistance from the United States Government or an agency or instrumentality thereof and the individual or firm is a party to the contract, a subcontractor, or an employee of a contractor or subcontractor.

(e) "Employee" means an individual who is under the jurisdiction of a chief of mission to a foreign country as provided under section 207 of the Foreign Service Act of 1980 (22 U.S.C. 3927) and who is—

(1) An employee as defined by section 2105 of title 5, United States Code;

(2) An officer or employee of the United States Postal Service or of the Postal Rate Commission;

(3) A member of a uniformed service who is not under the command of an area military commander; or

(4) An expert or consultant as authorized pursuant to section 3109 of title 5, United States Code, with the United States or any agency, department, or establishment thereof; but is not a national or permanent resident of the foreign country in which employed.

(f) "Family member" means any member of the family of an employee who is entitled to exemption from import limitation, customs duties, or taxes which would otherwise apply by virtue of his or her status as a dependent or member of the household of the employee.

(g) "Foreign country" means any country or territory, excluding the United States, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Trust Territory of the Pacific Islands, American Samoa, Guam, the Virgin Islands, and other territories and possessions of the United States.

(h) Except as otherwise provided by a chief of mission in policies, rules or procedures issued pursuant to § 136.5(b), an item shall be deemed of "minimal value" if its acquisition cost in U.S. dollars (or retail value if received as gift) is within the limit determined by the Administrator of General Services for "minimal value" of foreign gifts under 5 U.S.C. 7342, currently $180. For purposes of determining "minimal value," all constituent parts or components of an audio or visual system, automobile, boat, computer system, or other integrated machine, system or item of equipment must be valued as a single item even if acquired separately, except that spare or superseded parts (e.g., an old set of tires that has been replaced on vehicle) may be valued as separate items.

(i) "Personal property" means any item of personal property, including automobiles, computers, boats, audio and video equipment, and any other items acquired for personal use, except that items properly determined to be of "minimal value" shall not be subject to limitations on disposition except for purposes of § 136.4(d) or as prescribed in policies, rules or procedures issued by a chief of mission.

(j) "Profit" means any proceeds (including cash and other valuable consideration but not including amounts of such proceeds given as charitable contributions) for the sale, disposition or assignment of personal property in excess of the basis for such property.

§ 136.4 Restrictions on dispositions of personal property.

(a) An employee or family member shall not sell, assign or otherwise dispose of personal property within a foreign country except with the prior written approval of the chief of mission or designee, except where the category of dispositions has been authorized to be undertaken without prior written approval in policies, rules or procedures issued by the chief of mission (cf. 136.5(b)(1)).

(b) An employee or family member shall not retain any profit from the sale, assignment or other disposition within a foreign country of personal property that was imported into or purchased in that foreign country and that, by virtue of the official status of the employee, was exempt from import restrictions, customs duties, or taxes which would otherwise apply, when such sale, assignment or other disposition is made to persons not entitled to exemptions from import restrictions, duties, or taxes. An employee or family member shall not profit from an indirect disposition to persons not entitled to such exemptions, such as sale through a third country diplomat acting as a middleman, where the employee or family member knows or should know that the property is being acquired by the third party for resale to persons not entitled to exemptions, except that this restriction shall not apply to sales of personal property to official agencies of the foreign country in accordance with the laws or regulations of that country.

(c) Profits obtained from dispositions of personal property by an employee or family member that cannot be retained under paragraph (b) of this section, including any interest earned by the employee or family member on such profits, shall be disposed of within 90 days of receipt by contribution or gift as defined in section 170(c) of the Internal Revenue Code or by other similar contribution or gift to a bona fide charitable foreign entity as designated by the chief of mission pursuant to § 136.5(b)(11) of this section part.

(d) Except as authorized in advance by the chief of mission on a case-by-case basis, no employee or family member shall sell, assign or otherwise dispose of personal property within a foreign country that was not acquired for bona fide personal use. There shall be a presumption that property that is new, unused or held by the employee or family member in unusual or commercial quantities was not acquired for bona fide personal use. For purposes of this subsection, there is no exemption for items of minimal value (see § 136.3(h)).

(e) No employee or family member shall import, sell, assign or otherwise dispose of personal property within a foreign country in a manner that violates the law or regulations of that country or governing international law.

(f) Violations of the restrictions or requirements of paragraphs (a) through (e) shall be grounds for disciplinary actions against the employee in accordance with the employing agency's procedures and regulations. Employees shall be responsible for ensuring compliance with these regulations by family members.

(g) For purposes of computing profits on personal property dispositions subject to these regulations, proceeds received and costs incurred in a foreign currency shall be valued in United States dollars at the time of receipt or

payment at the rate of exchange that was in effect for reverse accommodation exchanges at U.S. missions at the time of such receipt or payment.

§ 136.5 Chief of mission policies, rules or procedures.

(a) Each chief of mission shall establish a procedure under which employees may request approval for the sale of personal property and for conversion of proceeds of such sale from local currency into U.S. dollars, if applicable. This procedure may be modified to meet local conditions, but must produce a documentary record to be held by the post of the following:

(1) The employee's signed request for permission to sell personal property and, if applicable, to convert local currency proceeds to U.S. dollars;

(2) A description of each item of personal property having more than minimal value, and the cost basis and actual sales price for each item;

(3) All profits received and whether profit is retainable;

(4) Donation to charities or other authorized recipients of non-retainable profits;

(5) Approvals to sell and, if applicable, to exchange proceeds, with any restrictions or refusals of the employee's request noted, signed by the chief of mission or designee; and

(6) For privately owned vehicle transactions, data on purchaser and statement that customs requirements have been met and title has been transferred or arranged with an agent identified on document.

(b) In order to ensure that due account is taken of local conditions, including applicable laws, markets, exchange rate factors, and accommodation exchange facilities, the chief of mission to each foreign country is authorized to establish policies, rules, and procedures governing the disposition of personal property by employees and family members in that country under the chief of mission's jurisdiction. Policies, rules and procedures issued by the chief of mission shall be consistent with the general restrictions set forth in § 136.4, and may include:

(1) Identification of categories of dispositions (e.g., sales of minimal value items) that may be made without prior written approval;

(2) Identification of categories of individuals or entities to whom sales of personal property can be made without restrictions on profits (e.g., other employees, third country diplomats), individuals or entities to whom sales can be made but profits not retained, and individuals or entities to whom sales may not be made;

(3) Requirements to report the total estimated and actual proceeds for all minimal value items, even if such items are otherwise exempted from limitations on profits of sale;

(4) Categories of items of personal property excluded from restrictions on disposition because generally exempt from taxation and import duties under local law;

(5) More restrictive definition of "minimal value" (see § 136.3(h) of this part);

(6) Limitations on manner of disposition (e.g., restrictions on advertising or yard sales);

(7) Limitations on total proceeds that may be generated by dispositions of personal property, including limitations on proceeds from disposition of "minimal value" items;

(8) Limitations on total profits that may be generated by dispositions of personal property, including limitations on profits from dispositions of "minimal value" items;

(9) Limitations on total proceeds from dispositions of personal property that may be converted into dollars by reverse accommodation exchange;

(10) Limitations on the timing and number of reverse accommodation exchanges permitted for proceeds of dispositions of personal property (e.g., only in last six months of tour and no more than two exchange conversions);

(11) Designation of bona fide charitable foreign entities to whom an employee or family member may donate profits that cannot be retained under these regulations.

(12) Designation of post officials authorized to approve on behalf of chief of mission employee requests for permission to sell personal property and requests to convert local currency proceeds of sale to U.S. dollars by reverse accommodation exchange.

(c) All policies, rules, and procedures that are issued by the chief of mission pursuant to paragraphs (a) and (b) of this section shall be announced by notice circulated to all affected mission employees and copies of all such policies, rules and procedures shall be made readily accessible to all affected employees and family members.

(d) Violations of restrictions or requirements established by a chief of mission in policies, rules, or procedures issued by a chief of mission pursuant to paragraphs (a) and (b) of this section shall be grounds for disciplinary actions against the employee in accordance with the employing agency's procedures and regulations. Employees shall ensure compliance by family members with policies, rules or procedures issued by the chief of mission.

§ 136.6 Contractors.

To the extent that contractors enjoy importation or tax privileges in a foreign country because of their contractual relationship to the United States Government, contracting agencies shall include provisions in their contracts that require the contractors to observe the requirements of these regulations and all policies, rules, and procedures issued by the chief of mission in that foreign country.

June 15, 1988.

George P. Shultz,

Secretary of State.

[FR Doc. 88-13847 Filed 6-16-88; 9:32 am]

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