22. Are FOIA fees collected and delivered to the servicing finance and accounting office within 30 calendar days after receipt?

Response: Yes___ No___ NA___
Remarks: 1

23. Are FOIA fees collected for technical data retained by the organization providing the technical data?

Response: Yes___ No___ NA___
Remarks: 1

EVENT CYCLE 3: Records Maintenance

Risk: Valuable records needed for court actions are destroyed or cannot be located.

Control Objective: Records containing "For Official Use Only" information are correctly marked and FOIA requests are properly maintained throughout their life cycle.

Control Technique: Ensure the prescribed policies and procedures are followed during the life cycle of information.

Test Questions:

1. Are records that fall within the purview of Exemption 2 through 9 marked "For Official Use Only" at the time of creation?

Response: ___ Yes ___ No ___ NA___
Remarks:

2. Are unclassified documents containing "For Official Use Only" information marked "For Official Use Only" in bold letters at least 3/16 of an inch high at the bottom of the outside of the front cover (if any), on the first page, and on the outside of the backcover (if any)?

Response: ___ Yes ___ No ___ NA___
Remarks:

3. Are individual pages containing both "For Official Use Only" and classified information marked at the top and bottom with the highest security classification of information appearing on the page?

Response: ___ Yes ___ No ___ NA___
Remarks:

4. Are photographs, films, tapes, slides, and microform containing "For Official Use Only" information so marked "For Official Use Only" to ensure recipient or viewer is aware of the information therein?

Response: ___ Yes ___ No ___ NA___
Remarks:

5. Is "For Official Use Only" material transmitted outside the Department of the Army properly marked "This document contains information EXEMPT FROM MANDATORY DISCLOSURE under the FOIA. Exemption _____ applies"?

Response: ___ Yes ___ No ___ NA___
Remarks:

6. Are permanently bound volumes of "For Official Use Only" information so marked on the outside of the front and back covers, title page, and first and last pages?

Response: ___ Yes ___ No ___ NA___
Remarks:

7. Is DA Label 87 (For Official Use Only Cover Sheet) affixed to "For Official Use Only" documents when removed from a file cabinet?

Response: ___ Yes ___ No ___ NA___
Remarks:

8. Do electrically transmitted messages contain the abbreviation "FOUO" before the beginning of the text?

Response: ___ Yes ___ No ___ NA___
Remarks:

9. Are "For Official Use Only" records stored properly during nonduty hours?

Response: ___ Yes ___ No ___ NA___
Remarks:

10. Are FOIA records maintained and disposed of in accordance with AR 25-400-2, The Modern Army Recordkeeping System (MARKS)?

Response: ___ Yes ___ No ___ NA___
Remarks:

---

1. Explain rationale for YES responses or provide cross-reference where rationale can be found. For NO responses, cross-reference to where corrective action plans can be found. If response is NA, explain rationale.

I attest that the above-listed internal controls provide reasonable assurance that Army resources are adequately safeguarded. I am satisfied that if the above controls are fully operational, the internal controls for this subtask throughout the Army are adequate.

Director of Information Systems for Command, Control, Communications, and Computers

FUNCTIONAL PROPONENT

I have reviewed this subtask within my organization and have supplemented the prescribed internal control review checklist when warranted by unique environmental circumstances. The controls prescribed in this checklist, as amended, are in place and operational for my organization (except for the weaknesses described in the attached plan, which includes schedules for correcting the weaknesses).

OPERATING MANAGER (Signature)

Kenneth L. Denton,

Alternate Army Liaison Officer with the Federal Register.

[FR Doc. 90-6294 Filed 3-22-90; 8:45 am]
BILLING CODE 3710-08-M

federal register

Friday
March 23, 1990

Part III

Department of Education

Indian Vocational Education Program; Invitation of Applications for New Awards Fiscal Year 1991; Notice

DEPARTMENT OF EDUCATION

Office of Vocational and Adult Education

[CFDA No: 84.101]

Indian Vocational Education Program; Invitation of Applications for New Awards Fiscal Year (FY) 1991

Note to Applicants: This notice is a complete application package. Together with the statute authorizing the program and applicable regulations governing this program, including the Education Department General Administrative Regulations (EDGAR), the notice contains all of the information, application forms, and instructions needed to apply for a grant under this competition.

Purpose of Program: To provide financial assistance to Indian tribes to plan, conduct, and administer projects, or portions of projects, that are authorized by and consistent with the Carl D. Perkins Vocational Education Act.

Eligible Applicants: The tribal organization of any Indian tribe which is eligible to contract with the Secretary of the Interior under the Indian Self-Determination and Education Assistance Act or under the Act of April 16, 1934.

Deadline for Transmittal of Applications: July 16, 1990.

Available Funds: $7,313,840.

Estimated Range of Awards: $50,000 to $500,000.

Estimated Average Size of Awards: $292,553.

Estimated Number of Awards: 25.

Note: The Department is not bound by any estimates in this notice.

Project Period: 12 to 36 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR, part 75 (Direct Grant Programs), part 77 (Definitions that Apply to Department of Regulations), part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments and Indian Tribal Governments), part 81 (General Education Provisions Act—Enforcement), part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants); and (b) The regulations for this program in 34 CFR part 410.

Selection Criteria: The Secretary uses the following selection criteria to evaluate applications for new grants under this competition. The maximum score for all of these criteria is 100 points. The maximum score for each criterion is indicated in parentheses. The Secretary assigns the 15 points reserved in 34 CFR 410.30(d) as follows: 5 points to the Selection criterion (a)—Need—in 34 CFR 410.31(a) for a total of 20 points for that criterion; 5 points to the Selection Criterion (b)—Plan of Operation—in 34 CFR 410.31(b) for a total of 25 points for that criterion; and 5 points to the Selection Criterion (e)—Evaluation Plan—in 34 CFR 410.31(e) for a total of 10 points for that criterion.

(a) *Need.* (20 points)

(1) The Secretary reviews each application for information that shows the need for the proposed project.

(2) The Secretary looks for information that shows—

(i) Specific evidence of the need for the proposed activity;

(ii) Information which shows how the need will be met; and

(iii) Ongoing and planned activities in the community which pertain to the need, where appropriate.

(b) *Plan of Operation.* (25 points)

(1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows—

(i) High quality in the design of the project;

(ii) An effective plan of management that ensures proper and efficient administration of the project;

(iii) A clear description of how the objectives of the project relate to the purpose of the program; and

(iv) The way the applicant plans to use its resources and personnel to achieve each objective.

(c) *Quality of key personnel.* (10 points)

(1) The Secretary reviews each application for information that shows the qualifications of the key personnel the applicant plans to use on the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director (if one is to be used);

(ii) The qualifications of each of the other key personnel to be used in the project; and

(iii) The time that each person referred to in paragraphs (c)(2) (i) and (ii) will commit to the project.

(3) To determine personnel qualifications, the Secretary considers experience and training, in fields related to the objectives of the project, as well as other information that the applicant provides.

(d) *Budget and cost effectiveness.* (10 points).

(1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows—

(i) The budget for the project is adequate to support the project activities; and

(ii) Costs are reasonable in relation to the objectives of the project.

(e) *Evaluation plan.* (10 points)

(1) The Secretary reviews each application for information that shows the quality of the evaluation plan for the project.

Cross-Reference. See 34 CFR 75.590 (Evaluation by the grantee).

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project and, to the extent possible, are objective and produce data that are quantifiable.

(f) *Adequacy of resources.* (5 points)

(1) The Secretary reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Secretary looks for information that shows—

(i) The facilities that the applicant plans to use are adequate; and

(ii) The equipment and supplies that the applicant plans to use are adequate.

(g) *Private sector involvement.* (10 points)

(1) The Secretary reviews each application for information that shows the involvement of the private sector.

(2) The Secretary looks for information that shows—

(i) The private sector involvement in the planning of the project; and

(ii) The private sector involvement in the operation of the project.

(h) *Employment opportunities.* (10 points)

(1) The Secretary looks for information and documentation of the extent to which, upon the completion of their training under this program, more than 65 percent of the trainees will be employed in jobs related to their training, (including military specialties) or will be pursuing additional training related to their training under this program.

(2) Information which shows that this employment is related to the tribal economic development plan.

(Approved by OMB Control No. 1830-0013)

Instructions for Transmittal of Applications: (a) If an applicant wants to apply for a grant, the applicant shall—

(1) Mail the original and two copies of the application on or before the deadline date to:

U.S. Department of Education,
Application Control Center, Attention: (CFDA #84.101), Washington, DC 20202–4725

or

(2) Hand deliver the original and two copies of the application by 4:30 p.m. (Washington, DC time) on the deadline date to:

U.S. Department of Education,
Application Control Center, Attention: (CFDA #84.101), Room #3633, Regional Office Building #3, 7th and D Streets, SW., Washington, DC

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: (1) The U.S. Postal Service does not uniformly provide a date postmark. Before relying on this method, an applicant should check with its local post office.

(2) The Application Control Center will mail a Grant Application Receipt Acknowledgment to each applicant. If an applicant fails to receive the notification of application receipt within 15 days from the date of mailing the application, the applicant should call the U.S. Department of Education Application Control Center at (202) 732–2495.

(3) The applicant must indicate on the envelope and—if not provided by the Department—in Item 10 of the Application for Federal Assistance (Standard Form 424) the CFDA number—and suffix letter, if any—of the competition under which the application is being submitted.

Application Instructions and Forms: The appendix to this application is divided into three parts plus a statement regarding estimated public reporting burden and various assurances and certifications. These parts and additional materials are organized in the same manner that the submitted application should be organized. The parts and additional materials are as follows:

Part I: Application for Federal Assistance (Standard Form 424 (Rev. 4–88)) and instructions.

Part II: Budget Information—Non-Construction Programs (Standard Form 424A) and instructions.

Part III: Application Narrative.

Additional Materials:

Estimated Public Reporting Burden.

Assurances—Non-Construction Programs (Standard Form 424B).

Certification regarding Debarment, Suspension, and Other Responsibility Matters: Primary Covered Transactions (ED Form GCS–008) and instructions.

Certification regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED Form GCS–009) and instructions.

Note: ED Form GCS–009 is intended for the use of grantees and should not be transmitted to the Department.

One or both of the following, as appropriate:

Certification Regarding Drug-Free Workplace Requirements: Grantees Other than Individuals (ED 80–0004).

Certification Regarding Lobbying for Grants and Cooperative Agreements (ED 80–0008).

Note: This form is required if requesting, making, or entering into a grant or cooperative agreement for more than $100,000.

Disclosure of Lobbying Activities (Standard Form LLL) (if applicable) and instructions; and Disclosure of Lobbying Activities Continuation Sheet (Standard Form LLL–A).

An applicant may submit information on a photostatic copy of the application and budget forms, the assurances, and the certifications. However, the application form, the assurances, and the certifications must each have an original signature. No grant may be awarded unless a completed application form has been received.

For Further Information Contact: Harvey Thiel or Karen Suagee, Special Programs Branch, Division of National Programs, Office of Vocational and Adult Education, U.S. Department of Education, 400 Maryland Avenue, SW. (Room 4512, Mary E. Switzer Building), Washington, DC. 20202–7242. Telephone (202) 732–2380 or 732–2379.

Program Authority: 20 U.S.C. 2313.

Dated: March 12, 1990.

Betsy Brand,

Assistant Secretary, Office of Vocational and Adult Education.

BILLING CODE 4000-01-M

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

2. DATE SUBMITTED	Applicant Identifier
3. DATE RECEIVED BY STATE	State Application Identifier
4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

1. TYPE OF SUBMISSION:

Application	*Preapplication*
☐ Construction	☐ Construction
☒ Non-Construction	☐ Non-Construction

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address *(give city, county, state, and zip code)*:	Name and telephone number of the person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER (EIN): ☐☐ – ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify): _____

8. TYPE OF APPLICATION:

☒ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other *(specify)*:

_____

9. NAME OF FEDERAL AGENCY:

U.S. Department of Education

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 8 4 . 1 0 1

TITLE: Indian Vocational Education Program

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(cities, counties, states, etc.)*:

13. PROPOSED PROJECT:		14. CONGRESSIONAL DISTRICTS OF:	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:		
a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:
1.	Self-explanatory.
2.	Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3.	State use only (if applicable).
4.	If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5.	Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7.	Enter the appropriate letter in the space provided.
8.	Check appropriate box and enter appropriate letter(s) in the space(s) provided: — "New" means a new assistance award. — "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date. — "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9.	Name of Federal agency from which assistance is being requested with this application.
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12.	List only the largest political entities affected (e.g., State, counties, cities).
13.	Self-explanatory.
14.	List the applicant's Congressional District and any District(s) affected by the program or project.
15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

SF 424 (REV 4-88) Back

OMB Approval No. 0348-0044

BUDGET INFORMATION — Non-Construction Programs

SECTION A – BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$
2.						
3.						
4.						
5. TOTALS		$	$	$	$	$

SECTION B – BUDGET CATEGORIES

6 Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY (1)	(2)	(3)	(4)	Total (5)
a. Personnel	$	$	$	$	$
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges (sum of 6a - 6h)					
j. Indirect Charges					
k. TOTALS (sum of 6i and 6j)	$	$	$	$	$
7. Program Income	$	$	$	$	$

Authorized for Local Reproduction

Standard Form 424A (4-88)
Prescribed by OMB Circular A-102

SECTION C - NON-FEDERAL RESOURCES

(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$
9.				
10.				
11.				
12. TOTALS (sum of lines 8 and 11)	$	$	$	$

SECTION D - FORECASTED CASH NEEDS

	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$	$	$	$	$
14. NonFederal					
15. TOTAL (sum of lines 13 and 14)	$	$	$	$	$

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT

(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTALS (sum of lines 16 -19)	$	$	$	$

SECTION F - OTHER BUDGET INFORMATION

(Attach additional Sheets if Necessary)

21. Direct Charges:	22. Indirect Charges:
23. Remarks	

SF 424A (4-88) Page 2
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

PART II -- BUDGET INFORMATION

INSTRUCTIONS FOR THE SF-424A

General Instructions

This form is designed so that application can be made for funds from the Indian Vocational Education program. Sections A and B should provide the budget for the first year of the project and Section E should present the need for Federal assistance in subsequent years.

(Note: Section D need not be completed to apply for these programs.) All application should contain a breakdown by the object class categories shown in Section B, Lines 6a through 6j.

Section A. Budget Summary

Line 1, Columns (a) through (g) -- Enter on Line 1 the catalog program title in Column (a) and the catalog program number in Column (b). Leave Columns (c) and (d) blank. Enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project, as appropriate.

Section B. Budget Categories

Line 6a through 6i -- Fill in the total requirements for Federal funds by object class categories for the first year of the project.

Line 6a -- Personnel: Show salaries and wages to be paid to personnel employed in the project. Fees and expenses for consultants must be included in Line 6f.

Line 6b -- Fringe Benefits: Include contributions for Social Security, employee insurance, pension plans, etc. Leave blank if fringe benefits to personnel are treated as part of the indirect

cost rate.

Line 6c -- Travel: Indicate the amount requested for travel of employee.

Line 6d -- Equipment: Indicate the cost of nonexpendable personal property which has a useful life of more than two years and an acquisition cost of $5,000 or more per unit.

Line 6e -- Supplies: Include the cost of consumable supplies to be used in this project. These should be items which cost less that $5,000 per unit with a useful life of less than two years.

Line 6f -- Contractual: Show the amount to be used for: (a) procurement contracts (except those which belong on other lines such as supplies and equipment listed above); and (b) sub-grants or payments for consultants and secondary recipient organizations such as affiliates, cooperating institutions, delegate agencies, etc.

Line 6g -- Construction: Construction expenses are allowable under the Vocational Education Indian Program (CFDA No. 84.101).

Line 6h -- Other: Indicate all direct costs not clearly covered by lines 6a through 6g. If there are trainee costs or stipends, enter the total cost of these expenses. The maximum allowance for stipends may be the larger of either the minimum wage prescribed by State or local law or the minimum hourly wage set by the Fair Labor Standards Act.

Line 6i -- Total Direct Charges: Show total of Lines 6a through 6h.

Line 6j -- Show the amount of indirect cost to be charged to the project.

(Note: Except for grants to Federally recognized Indian tribes, the indirect cost rate for training projects cannot exceed eight percent of total direct charges.)

Line 6k -- Enter the total of the amounts on Lines 6i and 6j.

Section E -- Budget Estimates of Federal Funds Needed for Balance of the Project

Line 16 -- Enter in Column (a) the catalog program title. In Columns (b) and (c), as appropriate, enter the amounts of Federal funds which will be needed to complete the project over the succeeding funding period(s) (usually in years).

Section F. Other Budget Information

Prepare a detailed Budget Narrative that explains, justifies, and/or clarifies the budget figures shown in Section A, B, and E.

Part III -- Application Narrative

Instructions for Part III -- Application Narrative

All applicants are urged to submit Application Narratives which are concise and clearly written. Before preparing the Application Narrative, applicants should read and become familiar with the law and the regulations covering the program to which they are applying.

Applicants should use the selection criteria for a program as an outline for preparing their Application Narrative, addressing the selection criteria in the order the criteria are listed. Applicants are encouraged to provide a table of contents and to number the pages of the Application Narrative. The Application Narrative should not exceed 25 double-spaced typed pages, (on one side only). Supporting documention (e.g., letters of support, footnotes, resumes, etc.) may be submitted as appendices to the Application Narrative.

Applicants are advised that:

(1) Under Section 75.217 of the Education Department General Administrative Regulations (EDGAR), the Department considers only information contained in the application in ranking applications for funding consideration. Letters of support sent separately from the formal application package are not considered in the review by the technical review panels.

(2) In reviewing applications, the technical review panel evaluates each application solely on the basis of the established technical review criteria. Letters of support contained in the application will strengthen the application

only insofar as they contain commitments which pertain to the established technical review criteria, such as commitment of resources and placement of successful completers.

ESTIMATED PUBLIC REPORTING BURDEN

Under terms of the Paperwork Reduction Act of 1980, as amended, and the regulations implementing that Act, the Department of Education invites comment on the public reporting burden for this collection of information. Public reporting burden for this collection of information is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. You may send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, Information Management and Compliance Division, Washington, D.C. 20202-4651; and to the Paperwork Reduction Project, OMB control number: 1830-0013, Office of Management and Budget, Washington, D.C. 20503. (Information collection approved under OMB Control Number 1830-0013. Expiration date: 3/31/91).

OMB Approval No. 0348-0040

ASSURANCES — NON-CONSTRUCTION PROGRAMS

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C.§§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

Standard Form 424B (4-88)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program andto purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

SF 424B (4-88) Back

Certification Regarding Debarment, Suspension, and Other Responsibility Matters Primary Covered Transactions

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, Section 85.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 Federal Register (pages 19160-19211). Copies of the regulations may be obtained by contacting the U.S. Department of Education, Grants and Contracts Service, 400 Maryland Avenue, S.W. (Room 3633 GSA Regional Office Building No. 3), Washington, D.C. 20202-4725, telephone (202) 732-2505.

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

(1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Organization Name PR/Award Number or Project Name

Name and Title of Authorized Representative

Signature Date

ED Form GCS-008, (REV.12/88)

Instructions for Certification

1. By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.

2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

4. The prospective primary participant shall provide immediate written notice to the department or agency to whom this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may contact the department or agency to which this proposal is being submitted for assistance in obtaining a copy of those regulations.

6. The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion–Lower Tier Covered Transactions," provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion Lower Tier Covered Transactions

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, Section 85.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 Federal Register (pages 19160-19211). Copies of the regulations may be obtained by contacting the person to which this proposal is submitted.

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Organization Name PR/Award Number or Project Name

Name and Title of Authorized Representative

Signature Date

ED Form GCS-009, (REV. 12/88)

Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion--Lower Tier Covered Transactions," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

Certification Regarding Drug-Free Workplace Requirements Grantees Other Than Individuals

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988, 34 CFR Part 85, Subpart F. The regulations, published in the January 31, 1989 Federal Register, require certification by grantees, prior to award, that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the agency determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment (see 34 CFR Part 85, Sections 85.615 and 85.620).

The grantee certifies that it will provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing a drug-free awareness program to inform employees about--

(1) The dangers of drug abuse in the workplace;
(2) The grantee's policy of maintaining a drug-free workplace;
(3) Any available drug counseling, rehabilitation, and employee assistance programs; and
(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will--

(1) Abide by the terms of the statement; and
(2) Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;

(e) Notifying the agency within ten days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction;

(f) Taking one of the following actions, within 30 days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted--

(1) Taking appropriate personnel action against such an employee, up to and including termination; or
(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

Organization Name _____ PR/Award Number or Project Name _____

Name and Title of Authorized Representative _____

Signature _____ Date _____

ED 80-0004

Certification Regarding Drug-Free Workplace Requirements
Grantees Who Are Individuals

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988, 34 CFR Part 85, Subpart F. The regulations, published in the January 31, 1989 Federal Register, require certification by grantees, prior to award, that their conduct of grant activity will be drug-free. The certification set out below is a material representation of fact upon which reliance will be placed when the agency determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment (see 34 CFR Part 85, Sections 85.615 and 85.620).

The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance in conducting any activity with the grant.

Organization Name (As Appropriate) PR/Award Number or Project Name

Printed Name

Signature Date

ED 80-0005

Certification Regarding Lobbying For Grants and Cooperative Agreements

Submission of this certification is required by Section 1352, Title 31 of the U.S. Code and is a prerequisite for making or entering into a grant or cooperative agreement over $100,000.

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, 'Disclosure Form to Report Lobbying,' in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact on which the Department of Education relied when it made or entered into this grant or cooperative agreement. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Organization Name | PR/Award (or Application) Number or Project Name

Name and Title of Authorized Representative

Signature | Date

ED 80-0008 12/89

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:
☐ a. contract
b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

2. Status of Federal Action:
☐ a. bid/offer/application
b. initial award
c. post-award

3. Report Type:
☐ a. initial filing
b. material change
For Material Change Only:
year _____ quarter _____
date of last report _____

4. Name and Address of Reporting Entity:
☐ Prime ☐ Subawardee
Tier _____, *if known*:
Congressional District, *if known*:

5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime:
Congressional District, *if known*:

6. Federal Department/Agency:

7. Federal Program Name/Description:
CFDA Number, *if applicable*: _____

8. Federal Action Number, *if known*:

9. Award Amount, *if known*:
$

10. a. Name and Address of Lobbying Entity
(if individual, last name, first name, MI):

b. Individuals Performing Services *(including address if different from No. 10a)*
(last name, first name, MI):

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

11. Amount of Payment *(check all that apply)*:
$ _____ ☐ actual ☐ planned

12. Form of Payment *(check all that apply)*:
☐ a. cash
☐ b. in-kind; specify: nature _____
value _____

13. Type of Payment *(check all that apply)*:
☐ a. retainer
☐ b. one-time fee
☐ c. commission
☐ d. contingent fee
☐ e. deferred
☐ f. other; specify: _____

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached: ☐ Yes ☐ No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____
Print Name: _____
Title: _____
Telephone No.: _____ **Date:** _____

Federal Use Only:

Authorized for Local Reproduction
Standard Form - LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 mintues per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity: _____ Page _____ of _____

Authorized for Local Reproduction
Standard Form - LLL-A

[FR Doc. 90-6627 Filed 3-22-90; 8:45 am]
BILLING CODE 4000-01-C

federal register

Friday
March 23, 1990

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 184

Direct Food Substances Affirmed as Generally Recognized as Safe; Chymosin Enzyme Preparation Derived From Escherichia Coli K-12; Final Rule

Pfizer Central Research, Pfizer, Inc.; Withdrawal of Food Additive Petition; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket Nos. 87G-0418 and 87F-0416]

Direct Food Substances Affirmed as Generally Recognized as Safe; Chymosin Enzyme Preparation Derived From Escherichia Coli K-12

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of chymosin preparation derived by fermentation from *Escherichia coli* K-12 is generally recognized as safe (GRAS). This action is in response to a petition filed by Pfizer Central Research, Pfizer, Inc.

EFFECTIVE DATE: March 23, 1990. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) of a certain publication in 21 CFR 184.1685(b) effective on March 23, 1990.

FOR FURTHER INFORMATION CONTACT: Eric L. Flamm, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), Pfizer Central Research (Pfizer) submitted a petition (GRASP 8G0337) requesting that its chymosin preparation (referred to as "chymosin" in the petition's filing notice that FDA published in the **Federal Register** of February 9, 1988 (53 FR 3792)), which is derived from the fermentation of a genetically modified *E. coli* K-12, be affirmed as GRAS as a direct human food ingredient. Chymosin is the principal enzyme in rennet, a GRAS food ingredient used for its milk-clotting activity, and is primarily responsible for that activity. Chymosin preparation is intended for use as a substitute for rennet.

To avoid confusion between chymosin the enzyme and chymosin the enzyme preparation (in which chymosin is the principal active component but which may also contain impurities), this document will henceforth use the term "chymosin" when referring to the enzyme and "chymosin preparation" when referring to the fermentation-derived chymosin enzyme preparation.

Pfizer submitted two petitions concerning chymosin preparation. In addition to GRASP 8G0337, it submitted a petition (FAP 8A4048) requesting that the food additive regulations be amended to provide for the safe use of genetically modified *E. coli* K-12 as a source of chymosin preparation (referred to as "chymosin" in the petition's filing notice that FDA published in the **Federal Register** of February 9, 1988 (53 FR 3792)), for use in food. The regulation that is the subject of this final rule is in response to the GRAS affirmation petition. Published elsewhere in this issue of the **Federal Register** is a document (Docket No. 87F-0416) announcing that Pfizer has withdrawn its food additive petition without prejudice to a future filing.

FDA gave interested parties an opportunity to submit comments concerning the GRAS affirmation petition to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. FDA received two comments in response to the notice. Both comments address whether the dairy industry needs new sources of chymosin. Neither comment contains any information relevant to the safety, functionality, environmental impact, or GRAS status of the food use of the subject chymosin preparation. Thus, the comments are not relevant to the agency's evaluation of chymosin preparation. FDA's authority in reviewing food additive and GRAS affirmation petitions is limited to questions about the safety and functionality of the substance at issue and does not include questions about the need for a new food ingredient (21 U.S.C. 348).

II. Standards for GRAS Affirmation

Pursuant to § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). In its petition, Pfizer has relied upon scientific procedures to establish that chymosin preparation is GRAS.

Rennet is an animal-derived enzyme preparation that is GRAS as specified in § 184.1685 (21 CFR 184.1685). Therefore, if published information shows that the principal active component of chymosin preparation is the same as that of rennet, and that the other components (i.e., impurities) of the chymosin preparation, which may differ from the other components (i.e., impurities) of rennet, do not render the use of the substance unsafe, then chymosin preparation derived from *E. coli* would present no more safety concern than rennet. If this is the case, FDA can affirm chymosin preparation derived from *E. coli* as GRAS for use as a replacement for rennet.

III. Safety

A. Introduction

Chymosin, also known as rennin, is the principal milk-clotting enzyme present in rennet (Ref. 1). Rennet is an enzyme preparation that will clot milk, forming it into curds and whey (Refs. 1 and 2). It is used to make cheese and other dairy products. It has a long and extensive history of safe use in food and has been affirmed by FDA as GRAS in § 184.1685 (48 FR 51151; November 7, 1983).

Food-grade rennet is an enzyme preparation that is derived from the fourth stomach of calves, kids, or lambs. Commercially, it is generally derived from unweaned calves by aqueous extraction. The aqueous extraction step is followed by purification steps and an acidification step to cleave prochymosin (the inactive precursor of chymosin) in the rennet into chymosin (Ref. 1).

There are two predominant forms of calf chymosin, chymosin A and chymosin B (Ref. 1). Foltmann et al. have shown that chymosin A and chymosin B differ by a single amino acid (Ref. 3). In this document FDA is using the terms "chymosin" to refer to either, or both, chymosin A and chymosin B.

Techniques developed in the last 15 years (frequently termed "recombinant DNA technology" or "cloning techniques") enable scientists to locate and to obtain a segment of deoxyribonucleic acid (DNA) containing a gene of interest. They are able to move that DNA segment into a vector (a self-replicating DNA molecule that is easy to manipulate) and then introduce it into a new host organism where it can be correctly expressed (that is, produce the protein that it would produce in the original organism). These techniques are

well-known to molecular biologists (see e.g., Refs. 4 and 5).

B. The Chymosin Component

Using cloning techniques, scientists in a number of different laboratories have identified the gene in the calf from which the chymosin in rennet is produced, the prochymosin gene (Refs. 6 through 8). Scientists have moved the calf prochymosin gene into *E. coli* (Refs. 6 through 10) as well as into other microorganisms (Refs. 11 through 13).

They have used a variety of techniques to demonstrate that they have cloned full-length copies of the correct gene. Such techniques include: (1) DNA sequencing, whereby the cloned putative prochymosin gene was shown to have the nucleotide sequence that encodes the amino acid sequence of prochymosin (Refs. 6 through 8); (2) nucleic acid hybridization, whereby the cloned DNA fragments or the ribonucleic acid (RNA) molecules made from the DNA fragments were shown to hybridize (i.e., specifically bind) with complementary DNA in the prochymosin gene (Refs. 7 through 12); and (3) physical mapping, whereby the cloned DNA fragments were shown to be large enough to contain the prochymosin gene and, when digested with appropriate DNA-cutting enzymes and run on gels that separate DNA fragments by size, were shown to yield the pattern of DNA fragments expected for prochymosin (Refs. 7 through 13).

The published evidence establishes that the new host organisms are able to use the prochymosin gene to produce prochymosin that has the same molecular weight as prochymosin found in calf rennet (Refs. 9 through 11 and 13 through 15). It also establishes that the prochymosin that is produced (cloned prochymosin) can be cleaved into chymosin (cloned chymosin) that has the same molecular weight and the same functional activity as chymosin found in calf rennet (Refs. 9, 10, and 12 through 15).

The molecular weights of prochymosin and chymosin were assayed using sodium dodecyl sulfate-polyacrylamide gel electrophoresis, a technique that enables one to determine the comparative molecular weight of proteins based on their rate of migration through the gel. Cloned prochymosin was found to migrate through these gels at the same rate as the prochymosin derived from calves (Refs. 9 through 11 and 13 through 15). Cloned chymosin was found to migrate through these gels at the same rate as the chymosin found in rennet (Refs. 9, 10, and 12 through 15).

The functional activity of chymosin that was measured was milk-clotting activity. Cloned chymosin was found to clot milk at the same rate as the chymosin in rennet under various temperatures, salt concentrations, and pH conditions (Refs. 9 through 15).

One safety concern raised by cloning is whether extraneous DNA, particularly DNA flanking the gene of interest, that could potentially encode extraneous harmful proteins may be cloned along with the gene of interest (i.e., prochymosin). However, the regulation stipulates that the substance being affirmed as GRAS is one that is produced using a production strain that is nontoxigenic (see § 184.1685(a)(2)). If the cloned DNA encodes a harmful substance that could render the enzyme preparation unsafe, the production strain would be toxigenic, and the substance produced would not be GRAS under § 184.1685(a)(2). Therefore, the agency finds that there is no basis for concern that the safety of the chymosin preparation will be compromised by contaminating proteins encoded by extraneous uncharacterized DNA cloned along with the prochymosin gene.

FDA notes that as a matter of good manufacturing practice, manufacturers using recombinant DNA technology should assure themselves that they have not inadvertently cloned extraneous protein-encoding DNA along with the prochymosin gene. Such assurance can come from reviewing the details of the cloning steps, such as the origin and sequence of the DNA fragments used in the cloning, and from full characterization of the final genetic constructs via techniques such as DNA sequencing. The agency points out that Pfizer's petition contains information demonstrating that it conducted these steps.

Based on the fact that published information demonstrates that chymosin produced from the cloned prochymosin gene has the same molecular weight and the same functional activity as the chymosin derived from calves, FDA concludes that the chymosin enzyme in chymosin preparation is the same as the chymosin enzyme in calf rennet. Therefore, FDA concludes that the chymosin enzyme in chymosin preparation is as safe as the chymosin enzyme in rennet.

C. Sources of Impurities

Enzyme preparations used in food-processing are usually not chemically pure but contain extraneous source (cellular) and processing material. The nature and amounts of these impurities in the finished enzyme preparation depend on the organism from which the enzyme is produced (the source or production organism), the fermentation materials and methods used to grow the production organism, and the materials and methods used to generate the finished enzyme preparation.

Both the source material and the manufacturing methods for producing chymosin preparation differ from those used to produce animal rennet. Therefore, the impurities in chymosin preparation will differ from those in rennet. The question thus is whether the source material or manufacturing methods for chymosin preparation will introduce impurities that would raise concerns about the safety of the preparation.

1. Processing steps

Researchers in a number of laboratories have published papers containing descriptions of methods that they used for producing chymosin preparation from microorganisms containing the calf prochymosin gene (e.g., Refs. 9 through 15). The methods described in these publications and in Pfizer's petition do not differ from each other in any significant way. The key steps in the methods, as described by Marston et al. (Ref. 15) and by Pfizer, are summarized below.

E. coli is grown in a liquid nutrient medium, then pelleted by centrifugation. The pelleted cells are resuspended in a small volume of buffer and burst open, releasing the prochymosin in the form of densely packed insoluble aggregates. The aggregates are recovered by a second centrifugation step, while most of the rest of the cellular protein and debris remain in suspension. The prochymosin is thus rapidly purified from the bulk of cellular material. Pfizer treats the aggregates with acid to kill residual cells and to degrade residual DNA. The prochymosin aggregates are solubilized by denaturation in an alkaline urea solution. The prochymosin is renatured by decreasing the alkalinity and diluting out the urea and further purified by ion-exchange chromatography. The prochymosin is converted to chymosin, the active form of the enzyme, by suspension in a pH 2 acid solution for an hour. The final chymosin preparation is a clear solution.

FDA finds that the manufacturing method does not require the use of any processing materials that are not GRAS or approved food additives. Accordingly, it is specifying in the regulation that the substance being affirmed as GRAS is one that is produced using only processing materials that are GRAS substances or food additives approved for use in this type of process (see § 184.1685(a)(2)). Therefore, the agency concludes that the

manufacturing steps will not introduce impurities into the enzyme preparation that will adversely affect the safety of the preparation.

2. Production organism

The source material for the chymosin in chymosin preparation is *E. coli* K–12. *E. coli's* natural habitat is the large intestine of humans and animals, where it is found at 1 million to 100 million organisms per gram of intestinal contents (Ref. 16). *E. coli* K–12 is a laboratory strain that, through longtime propagation in the laboratory, has lost a number of the traits necessary for colonization of, and therefore survival in, the intestinal tract (Ref. 17).

E. coli K–12 is one of biology's most extensively studied microorganisms. It has been shown to be nonpathogenic and nontoxigenic in studies in which it has been fed to humans and laboratory animals (see, e.g., Refs. 16 and 17) and in detailed studies of its phenotypic and genotypic traits (see, e.g., Refs. 16 through 18). For example, Gorbach (Ref. 16), Curtiss (Ref. 17), and Smith (Ref. 18) have reported their own and others' failed attempts to implant *E. coli* K–12 in the human intestine, an initial step for pathogenicity. In none of the experiments were researchers able to isolate the strain from the feces of volunteers 1 to 6 days after they were fed high doses (10^{9}–10^{10} live organisms) of various strains of *E. coli* K–12. In none of the experiments did the volunteers become sick as a result of their ingestion of the organisms.

Gorbach (Ref. 16) discussed six factors necessary for an organism to be pathogenic: (1) Survival in the environment, (2) a mechanism for penetrating the skin or mucosal surface, (3) multiplication within the host, (4) systemic spread within the host, (5) resistance to host defense mechanisms, and (6) production of a toxin or some other mechanism to damage the host to produce disease symptoms. He noted that a lack of any one of these characteristics will render the microorganism nonpathogenic, and that, based on the available evidence, *E. coli* K–12 is deficient in every one of these factors (Ref. 16). Gorbach also noted that in the 30 years that *E. coli* K–12 has been used in genetics research, there have been no reported cases of laboratory-acquired infections from this organism (Ref. 16).

As corroborative evidence of the safety of chymosin preparation, Pfizer submitted two unpublished short-term in vivo studies conducted on its enzyme preparation, a 5-day feeding study in dogs and a 1-month gavage study in rats (Ref. 19). No adverse effects were observed in these studies at any dose fed.

Some *E. coli* K–12 strains, such as those that are used by Pfizer and others (e.g., Refs. 9, 10, and 14) to produce chymosin preparation, do contain marker genes that encode resistance to clinically useful antibiotics. Such genes potentially could be transferred to other microorganisms with which the production strain or its DNA comes into contact. However, as previously described, the isolation of the enzyme as an intracellular insoluble aggregate results in the destruction of the microorganism and in the elimination of most cellular material, including these marker genes (Ref. 15). Additionally, the two acid treatment steps in the manufacturing process inactivate residual cells and degrade residual DNA, including marker genes, that remain in the enzyme preparation (Ref. 20).

As corroborative evidence that the enzyme preparation does not contain gene-size DNA fragments or transformable DNA (that is, DNA that a microorganism can take up from its surroundings and functionally incorporate into its own DNA), Pfizer submitted data from several unpublished experiments, including a gel electrophoresis/DNA hybridization assay and a transformation assay. In the electrophoresis experiment, DNA fragments were sized based on their differential rates of migration through the gel and quantitated based on their level of hybridization with labeled complementary DNA. No DNA fragments large enough to contain an intact gene encoding antibiotic resistance were detected in the enzyme preparation (Ref. 19).

In the transformation assay, bacterial cells were mixed with DNA under optimized conditions and assayed to see if they had picked up the antibiotic resistance encoded by the DNA. Cells mixed with the enzyme preparation did not become antibiotic resistant (Ref. 19).

Based on the above discussion, FDA concludes that chymosin preparation manufactured in conformity with § 184.1685(a)(2) will not contain DNA encoding resistance to antibiotics at levels that would provide any safety concern. FDA concludes that *E. coli* K–12 is safe for use as a source of food-grade chymosin preparations, and that impurities resulting from its use in the production of chymosin preparation will not affect the safety of the chymosin preparation.

IV. Specifications

The agency finds that, because the principal active ingredient of chymosin preparation and rennet are the same, and because the impurities in chymosin preparation do not provide any basis for concern that the use of the preparation may not be safe, the general and additional requirements given for rennet and other enzyme preparations in the "Food Chemicals Codex," 3d Ed. (1981), pp. 107–110, are adequate for defining minimum criteria for a food-grade chymosin preparation derived from *E. coli* K–12. FDA is amending § 184.1685(b) to reference pp. 109 and 110 of the "Food Chemicals Codex," 3d Ed. (1981), as well as pp. 107 and 108.

V. Conclusions

The agency has evaluated all available information and finds, based upon the published and corroborative evidence discussed above, that the active principal ingredient in the chymosin preparation is the same as that in rennet, and that when the preparation is manufactured in accordance with § 184.1685(a)(2), the source organism and manufacturing process will nor introduce impurities into the preparation that would provide a basis for concern that the use of the preparation may not be safe. Therefore, the agency concludes, based upon scientific procedures, that the chymosin preparation derived by fermentation from *E. coli* K–12 and described in the regulation below is GRAS for use as a replacement for rennet.

VI. Environmental Effects

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above).

VII. Economic Effects

FDA, in accordance with the Regulatory Flexibility Act, has considered the effects that this regulation would have on small entities, including small businesses, and has determined that the effect of this regulation is to provide for the use of fermentation-derived chymosin for both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this final rule and has determined that this rule will not be a major rule as defined by that Order.

The agency's finding of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Foltmann, B., "Prochymosin and Chymosin (Prorennin and Rennin)," *Methods in Enzymology*, 19:421–436, 1970.
2. Burgess, K., and M. Shaw, "Dairy," in *"Industrial Enzymology,"* T. Godfrey and J. Reichelt, eds., The Nature Press, New York, pp. 260–265, 1983.
3. Foltmann, B. et al., "The Primary Structure of Calf Chymosin," *Journal of Biological Chemistry*, 254:8447–8456, 1979.
4. Watson, J.D. et al., *"Molecular Biology of the Gene,"* Benjamin/Cummings Publishing Co., Inc., Menlo Park, CA, pp. 65–94, 202–213, 1987.
5. Murray, K., "Genetic Engineering and its Applications," in *"Basic Biotechnology,"* J. D. Bu'Lock and B. Kristiansen, eds., Academic Press, London, pp. 483–508, 1987.
6. Harris, T. J. R. et al., "Molecular Cloning and Nucleotide Sequence of cDNA Coding for Calf Preprochymosin," *Nucleic Acids Research*, 10:2177–2187, 1982.
7. Hidaka, M. et al., "Cloning and Structural Analysis of the Calf Prochymosin Gene," *Gene*, 43:197–203, 1986.
8. Moir, D. et al., "Molecular Cloning and Characterization of Double-stranded cDNA Coding for Bovine Chymosin," *Gene*, 19:127–138, 1982.
9. Emtage, J.S. et al., "Synthesis of Calf Prochymosin (Prorennin) in *Escherichia coli*," *Proceedings of the National Academy of Sciences*, 80:3671–3675, 1983.
10. McCaman, M.T., W.H. Andrews, and J.G. Files, "Enzymatic Properties and Processing of Bovine Prochymosin Synthesized in *Escherichia coli*," *Journal of Biotechnology*, 2:177–190, 1985.
11. Goff, C.G. et al., "Expression of Calf Prochymosin in *Saccharomyces cerevisiae*," *Gene*, 27:35–46, 1984.
12. Cullen, D. et al., "Controlled Expression and Secretion of Bovine Chymosin in *Aspergillus nidulans*," *Bio/Technology*, 5:369–376, 1987.
13. Mellor, J. et al., "Efficient Synthesis of Enzymatically Active Calf Chymosin in *Saccharomyces cerevisiae*," *Gene*, 24:1–14, 1983.
14. Kawaguchi, Y. et al., "Production of Chymosin in *Escherichia coli* Cells and its Enzymatic Properties," *Agricultural and Biological Chemistry*, 51:1871–1877, 1987.
15. Marston, F.A.O. et al., "Purification of Calf Prochymosin (Prorennin) in *Escherichia coli*," *Bio/Technology*, 2:800–804, 1984.
16. Corbach, S.L., "Recombinant DNA: An Infectious Disease Perspective," *Journal of Infectious Diseases*, 137:615–623, 1978.
17. Curtiss, R., "Biological Containment and Cloning Vector Transmissibility," *Journal of Infectious Diseases*, 137:668–675, 1978.
18. Smith, H.W., "Is It Safe to Use *Escherichia coli* K–12 in Recombinant DNA Experiments?," *Journal of Infectious Diseases*, 137:655–660, 1978.
19. Petition 8C0337.
20. Lehninger, A.L., *"Biochemistry,"* Worth Publishers, New York, p. 256, 1970.

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1685 is revised to read as follows:

§ 184.1685 Rennet (animal-derived) and chymosin preparation (fermentation-derived).

(a) (1) Rennet and bovine rennet are commercial extracts containing the active enzyme rennin (CAS Reg. No. 9001–98–3), also known as chymosin (International Union of Biochemistry Enzyme Commission (E.C.) 3.4.23.4). Rennet is the aqueous extract prepared from cleaned, frozen, salted, or dried fourth stomachs (abomasa) of calves, kids, or lambs. Bovine rennet is the product from adults of the animals listed above. Both products are called rennet and are clear amber to dark brown liquid preparations or white to tan powders.

(2) Chymosin preparation is a clear solution containing the active enzyme chymosin (E.C. 3.4.23.4). It is derived, via fermentation, from a nonpathogenic and nontoxigenic strain of *Escherichia coli* K–12 containing the prochymosin gene. The prochymosin is isolated as an insoluble aggregate that is acid-treated to destroy residual cellular material and, after solubilization, is acid-treated to form chymosin. It must be processed with materials that are generally recognized as safe, or are food additives that have been approved by the Food and Drug Administration for this use.

(b) Rennet and chymosin preparation meet the general and additional requirements for enzyme preparations of the "Food Chemicals Codex," 3d Ed. (1981), pp. 107–110, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or are available for inspection at the Office of the Federal Register, 1100 L Street NW., Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: In cheeses as defined in § 170.3(n)(5) of this chapter; frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; and milk products as defined in § 170.3(n)(31) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: March 14, 1990.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–6600 Filed 3–22–90; 8:45 am]

BILLING CODE 4160–01–M