CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Chloridiazepoxide, Diazepam, Oxazepam, Clorazepate, Flurazepam and Chlordiazepoxide in Schedule IV

On January 22, 1976, the Administrator of the Drug Enforcement Administration issued a notice of proposed rulemaking to amend §1308.14 of Title 21 of the Code of Federal Regulations (CFR) to include chloridiazepoxide, chlordiazepoxide, oxazepam, clorazepate, flurazepam and clonazepam in Schedule IV of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801-966). This notice was published in the Federal Register on January 27, 1976 (40 FR 4016-4017), and provided an opportunity for all interested persons to submit comments, objections and requests for a hearing on the matter no later than March 26, 1976.

The notice further provided that if objections submitted present reasonable grounds for the proposed rule not to be finalized, and if a hearing is requested, such would be held as soon as the matter could be heard before the Drug Enforcement Administration. The notice also stated that if all interested parties waive their opportunity to request or participate in a hearing, the Administrator may, without a hearing, issue his final order pursuant to 21 CFR 1308.48 after giving consideration to written comments submitted.

Numerous comments were received by the Hearing Clerk, Office of the Administrative Law Judge, Drug Enforcement Administration; however, none of them contained a request for a hearing in this matter, and no such requests have been submitted in any other fashion. Therefore, the Administrator of the Drug Enforcement Administration has determined that all interested persons are deemed to have waived the opportunity for a hearing in the matter, and a final order with respect to controlling the above substances shall be issued without a hearing, but shall be based upon a full consideration of all comments received in response to the January 27, 1976 notice of proposed rulemaking.

Among the comments received was a letter, dated March 26, 1976, from Dr. William S. Langeland, submitted in behalf of Wyeth Laboratories Inc., manufacturer of Serax (oxazepam). In the letter, Wyeth presented significant comments and objections to the notice of January 27, 1975, regarding oxazepam. These comments and objections are distinguished by their formality and substantiality from other comments received, and merited a response by the Drug Enforcement Administration. The comments and objections raised by Wyeth may be summarized as follows:

1. The present rule which indicates that the potential for abuse of oxazepam is equivalent to that of chloridiazepoxide (Librium) is not identified in either the November 25, 1974 letter from Dr. Charles C. Edwards, then Assistant Secretary for Health, Department of Education, and Welfare (HEW), nor its enclosure, entitled Scheduling Recommendations for Benzodiazepines (hereinafter Recommendations).

2. As evidence of his contention that HEW does not identify "present evidence," Wyeth states that it can not reconcile the affirmative conclusions of HEW in the areas of tolerance, psychic and physical dependence of oxazepam, with the negative conclusions of Drs. Isbell and Chruscel [sic] to which HEW refers in the tabulated chart contained in Recommendations.

3. Recommendations concludes that oxazepam has a potential for abuse equivalent to chloridiazepoxide and diazepam, and has a dependence liability which does not appear to differ from that of other benzodiazepines. Recommendations' conclusions are supported by an attached chart entitled Benzodiazepines, which displays "yes" in the categories of physical dependence, psychological dependence (Graum), and tolerance relative to chloridiazepoxide, diazepam and oxazepam. This chart cites as a reference Isbell, E. and Chruscel, T. L.: Dependence Liability of "Non-Narcotic" Drugs, page 46, 1970, yet this reference does not yield the same conclusions in the above categories as does Recommendations.

4. The chart by HEW further displays "yes" in the categories of anti-metrazol, rolad, anti-shaking and anti-maximal electroshock for all the benzodiazepines, including oxazepam. It cites as a reference for these conclusions, The Benzodiazepine literature of Gaessmann, Musuhn, and Randall, page 22, 1972. However, it does not appear from page 22 of this source that oxazepam was studied for such characteristics.

5. Paragraphs (1), (4), (5) of the HEW document, Recommendations, state that actual abuse of oxazepam is less than that of chloridiazepoxide and diazepam. Recommendations cites thirty-three overdose reports within the past ten years. This exemplifies that, at most, there has been only isolated and non-therapeutic abuse of oxazepam.

6. HEW concludes in its March 25, 1974 letter and in Recommendations that the dependence syndrome for oxazepam does not appear to differ from that of other benzodiazepines, yet HEW has not documented, in its letter nor in Recommendations, the basis for its conclusion, except to report seven cases of physical dependence and one possible case of psychological dependence.

7. For its conclusion on psychomotor dependence, HEW relies upon the results of self-administration tests in monkeys using oxazepam. This methodology is not scientifically conclusive, since the subject animals may have been self-administering oxazepam for other than drug effects.

8. Contrary to Recommendations paragraph (2), page 6, wherein HEW states that chloridiazepoxide, diazepam and oxazepam can all be metabolized in vivo to oxazepam, recent studies indicate oxazepam is not a metabolite of those benzodiazepines. Greenblatt, et al., Pharmacokinetics in Clinical Medicine: Oxazepam versus Other Benzodiazepines (1976) further states that oxazepam has a relatively short half-life, and suggests little accumulation during chronic dosage, unlike the above-referenced benzodiazepines.

9. HEW apparently means, in its statement in Recommendations, paragraph (6), page 7, regarding oxazepam's risk to public health, that if there was abuse of oxazepam it would be like the abuse of chloridiazepoxide and diazepam. Since it is not, there is no present risk to the public health with oxazepam.

10. DEA has seen fit to propose oxazepam for control in Schedule IV only because of the compulsion to control chloridiazepoxide and diazepam.

11. As a legal matter, the statutory procedure required by section 201(b) of the Controlled Substances Act to be followed in drug control proceedings such as the present one, has not been complied with since DEA did not gather relevant data on oxazepam and did not formally request from the Secretary of HEW a scientific and medical evaluation and recommendation regarding oxazepam.

12. Fair and orderly decision-making steps were not followed in the care of oxazepam. These steps customarily include furnishing affected parties copies of DEA'S Initial Data Report and Initial Data Report on oxazepam for an HEW evaluation and recommendation, so that all concerned could respond to preliminary positions taken by DEA regarding oxazepam.

13. The proposal to include oxazepam in Schedule IV is based upon "class..."
action" approach taken by the Food and Drug Administration of HEW, without specific origins of authority for such approach, to the Petitioner's legislative history, or regulations of DEA.

14. Present evidence of abuse of oxazepam is lacking, and therefore control of oxazepam at this time is unnecessary. DEA has the burden of proof in this regard, which it has failed to demonstrate in the notice of proposed rulemaking.

RESPONSE OF THE DRUG ENFORCEMENT ADMINISTRATION

DEA has fully considered the comments and objections submitted by Wyeth, as summarized above, and has undertaken an analysis of the data and information which served as the basis for the notice of proposed rulemaking regarding oxazepam. As a result, the Administrator of DEA has made the following determinations, responsive to the Wyeth comments and objections summarized above.

"Present evidence" that the potential for abuse of oxazepam is equivalent to that of chloridiazepoxide and diazepam, which are Schedule IV drugs under the Controlled Substances Act of 1970 (21 U.S.C. 811), was identified in its November 25, 1974 transmittal to DEA, actually consists of data contained in the New Drug Application for oxazepam (Cordarone), chloridiazepoxide (Librium) and diazepam (Vallum), scientific and medical literature collected and reviewed by members of the FDA staff, material submitted by DEA to HEW on August 14, 1973, and to FDA on June 28, 1974, material submitted to FDA by the FDA 1974 Controlled Substances Advisory Committee for their consideration by Wyeth Laboratories, Inc., Abbott Laboratories, and Hoffman-La Roche Inc., an analysis of the proceedings of meetings of the FDA 1974 Controlled Substances Advisory Committee on April 25-26, 1974, and on June 24-25, 1974.

Of this data, the scientific and medical literature reviewed by FDA Staff included numerous articles.

In addition to, and more current than, Isbell, H. and Chrulsel, T.L.: Dependence Liability of "Non-Narcotic" Drugs, p. 49, in "The Dependence Liability of Oxazepam, the above recent scientific literature has permitted HEW to affirmatively conclude that oxazepam possesses tolerance, psychic and physical dependence characteristics equivalent to that of other benzodiazepines.

In fact, the Isbell and Chrulsel, in their 1970 article, recognized and anticipated that, in time, it may be established that oxazepam possesses tolerance, psychic and physical dependence equivalent to that of chloridiazepoxide and diazepam.

The change in recommendations provides further concern to Wyeth, which suggests that HEW does not identify the basis for its conclusions that oxazepam possesses tolerance, psychic and physical dependence characteristics equivalent to that of other benzodiazepines.

Wyeth's own labeling for Serax states that "In mice, Serax asserts an anticonvulsant and barbiturate-like activity at fifty percent effective doses of about 0.5 mg per kg, orally." Wyeth alleges that HEW has not provided the Administrator of DEA with data on actual abuse of oxazepam sufficient to warrant control, citing the thirty-three FDA drug reports and the seven cases of physical dependence referred to by HEW in page 6 of Recommendations as evidence of the paucity of actual abuse statistics, and as proof that there exists only isolated and occasional nontherapeutic abuse of oxazepam.

However, actual abuse, to the extent it exists, merely represents the fruition of a drug's potential for abuse. Indeed, demonstrating either is sufficient to satisfy the control requirements of sections 201(c)(1)(A) and 202(a)(3) of the Act that the Attorney General consider "oxazepam's" actual or relative potential for abuse.

The drugs referred to by Wyeth demonstrate oxazepam's potential for abuse. The above thirty-three overdose reports and seven cases of dependence are some, but not all, of the evidence that oxazepam has also been the subject of actual abuse. In determining their significance, it must be noted that these reports are of the type which are required to be submitted by manufacturers of a drug for which an approved NDA has been issued. These reports are therefore based upon knowledge, coming to the manufacturer, from time to time, of adverse effects of their drugs, and are not generated in the laboratory in fulfillment of a condition required under their NDA. The gathering and reporting of such information by the drug manufacturer is not for the purpose of evaluating the drug for placement into a Schedule under the Act, although the primary objective is to be utilized for that purpose by HEW and DEA. These reports, generally required to be submitted annually for NDA purposes, were requested from Wyeth by the FDA earlier than when due, so that they could be submitted along with other relevant material to the FDA 1974 Controlled Substances Advisory Committee.

The Benzdiazepines, page 32, does not reveal any information regarding these properties of oxazepam. Consequently, the reference to page 32 of The Benzdiazepines is a typographical error, and should appear as p. 42. Actually, the pages dealing with the properties of oxazepam are pages 41-43. Moreover, Wyeth's own labeling for Serax states that "In mice, Serax asserts an anticonvulsant and barbiturate-like activity at fifty percent effective doses of about 0.5 mg per kg, orally."
survey taken by DEA in August 1974, has revealed that samples of oxazepam were submitted to State and local police laboratories at least 101 times. In seven Federal cases, oxazepam was being used with such drugs as amphetamine, barbiturates, cocaine, heroin, LSD, marihuana, MDA and phencyclidine. Serax has been offered for sale in large quantities, primarily to Federal narcotics agents. New York, Ohio and Virginia have reported that Serax has achieved "street status" and sold illicitly for as much as two dollars per capsule.

Therefore, the statement by HEW in recommendations that the inclusion of oxazepam has been reported, is substantiated.

Wyeth comments that HEW cites no evidence of a dependence syndrome with oxazepam, except for seven cases, and therefore, has no proof that oxazepam is equivalent to other benzodiazepines in producing dependence.

However, the labeling for Serax, Wyeth's brand of oxazepam states that withdrawal occurs following abrupt discontinuance of excessive doses of Serax are similar to those seen with the barbiturates. In 1968, it was reported that chloridiazepoxide and diazepam produced withdrawal symptoms similar to those seen with the barbiturates. It can be concluded therefore, that oxazepam produces a withdrawal syndrome similar to that produced by other benzodiazepines. The American Medical Association has reached a similar conclusion.

For its conclusion on psychological dependence, HEW relied in part upon the results of self-administration tests in monkeys of the evidence was obtained from human case reports. Although the animal methodology is not by itself conclusive, data obtained therefrom is certainly relevant to the support of the HEW conclusion.

In the self-administration study referred to above, the animals did not self-administer saline when available. This clearly shows that the animals in the study self-administered the drugs for their effect, contrary to Wyeth's comment that "... the animal subject may be administering for reasons other than drug effect ..." and demonstrates the behavior reinforcing properties of oxazepam, as well as chloridiazepoxide, diazepam, clorazepate and flurazepam. This method has been accepted by the WHO Expert Committee on Drug Dependence and is support for HEW's reliance on this manner of demonstrating psychic dependence of oxazepam.

Wyeth's comment that oxazepam is not an active metabolite of chloridiazepoxide, diazepam, clorazepate, is ill-founded, for the reference which they cite as authority for that comment actually deals with the kinetics of drug distribution, not metabolism.

In fact, Wyeth has stated in contradiction to its own comments, that "... part of the activity of diazepam (Valium) may be due to its major metabolite oxazepam ...". Recent scientific literature and other scientific materials not only support this statement by Wyeth regarding diazepam, but further indicate that chloridiazepoxide is metabolized to demoxepam and then to oxazepam. Therefore, Wyeth's comments regarding metabolism to oxazepam do not appear to be sufficient or persuasive in rebutting the drug oxazepam from other benzodiazepines in this regard.

Regarding Wyeth's comment that there is no present risk to the public health with oxazepam, the above clearly demonstrates that it has a potential for abuse, equivalent to other benzodiazepines, and that abuse may lead to physical or psychic dependence. Surely a drug possessing these characteristics poses a serious threat to the public health which could be diminished by imposing appropriate controls provided by the Act. The imposition of controls would be inappropriate if the drug creates no danger to the public health.

The decision to proposed Federal regulatory control of oxazepam in Schedule IV has been based upon the six categories of material set forth in the January 27, 1975 notice of proposed rulemaking, including the above-referenced information, and not from any "compulsion" to control Librium and Valium, as Wyeth suggests. This proposal was based upon the fact that the identified oxazepam, individually as having met the require-ments of sections 201 (b), (c), and 202 (a) of the Act, so as to allow its inclusion in Schedule IV. Because oxazepam shares, with other benzodiazepines, characteristics which justify inclusion in Schedule IV, there is no reason to issue a proposal to include them all in Schedule IV. This may constitute a "class action" for control, as Wyeth describes it, yet oxazepam, as with each member of the "class," has been individually evaluated and, as the above data clearly demonstrates, its individual characteristics rather than anything else warrants its inclusion in Schedule IV.

Wyeth comments that the HEW transmission of November 28, 1974, on uniform oxazepam was premature, and without legal authority, because it was not preceded by a DEA request that HEW recommend oxazepam for control, nor by DEA gathering necessary data relative to such a request. Wyeth specifically states that DEA did not provide the FDA 1974 Controlled Substances Advisory Committee with such data on oxazepam.

It is true, as Wyeth states, that before initiating proceedings to control a drug, which can be initiated only by the Attorney General (i.e., the Administrator of the Drug Enforcement Administration), DEA must gather the necessary data, and request HEW's evaluation and recommendation. Proceedings to control oxazepam were initiated on January 27, 1975 when the notice of proposed rulemaking was published in the Federal Register, 21 CFR 1308.02(c); 40 FR 4016-4017. Frapporti prepared a draft proposal dated June 28, 1974, and pursuant to a request from the FDA Drug Abuse Staff, DEA transmitted law enforcement data, drug abuse statistics, and other data relative to oxazepam. FDA had already advised DEA that it was evaluating oxazepam for a DEA request, and in fact had convened its Controlled Substances Advisory Committee, which was considering making this recommendation. It was understood by DEA that this material was to be forwarded to this Committee to assist it in deciding whether to recommend to FDA that oxazepam be controlled under the Act.

Knowing that a control decision on oxazepam was the object of FDA's request for DEA drug abuse data, and, moreover, knowing that FDA and its Advisory Committee were soon to arrive at a control decision on oxazepam, DEA saw no useful purpose to be served by submitting, with this data, a formal request to the Secretary asking him to commence studying oxazepam with a view towards recommending schedule controls.

Under such circumstances, and especially in view of the fact that DEA gathered and transmitted necessary data on oxazepam before initiating the present proceedings, it would be exalting form over substance to render the proceeding to control oxazepam moot under the guise of statutory non-compliance.


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4. Abuse of chlordiazepoxide, diazepam, oxazepam, clorazepate, flurazepam, and clonazepam may lead to limited physical or mental dependence or psychological dependence relative to the drugs or other substances in Schedule III.

3. Therefore, the authority vested in the Attorney General by section 201(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by § 100.10 of Title 28 of the Code of Federal Regulations, allows that, upon approval of the New Drug Application for clonazepam by FDA, Section 1308.14 of Title 21 of the Code of Federal Regulations (CFR) be amended to read:

§ 1308.14 Schedule IV.

4. (b) Depressants. Unless specifically excepted or unless listed in another schedule, any compound, mixture, or preparation which contains any quantity of the following substances, if purchased, sold, transported, or dispensed by or with the authority of the Administrator of the Department of Health, Education, and Welfare, on Schedule IV of the Controlled Substances Act:

(1) Barbituates
(2) Chlordiazepoxide
(3) Chloral hydrate
(4) Chlorazepate
(5) Diazepam
(6) Ethchlorvynol
(7) Flurazepam
(8) Methaqualone
(9) Miltown
(10) Meprobamate
(11) Mephenesin
(12) Methaqualone
(13) Methaqualone
(14) Methyprylon
(15) Oxazepam
(16) Propyclonate
(17) Psyllium

5. (a) The issuing of a letter approving the New Drug Application for clonazepam, by FDA, has occurred simultaneously with the issuing of this order, which is effective as follows:

6. Effective Dates

1. Registration. Any person who manufactures, distributes, dispenses, imports, or exports, chlordiazepoxide, diazepam, oxazepam, clorazepate, flurazepam and clonazepam shall have a potential for abuse relative to the other substances currently listed in Schedule IV.

7. Abstinence. Any person who manufactures, distributes, dispenses, imports, or exports, chlordiazepoxide, diazepam, oxazepam, clorazepate, flurazepam or clonazepam, who proposes to engage in such activities, shall submit an application for registration to conduct such activities in accordance with Parts 1301 and 1301.7 of Title 21 of the Code of Federal Regulations on or before July 2, 1975.

8. Criminal Liability. Pursuant to Title 21 of the Code of Federal Regulations, Section 1001 of the Controlled Substances Act, as amended, this order applies to any activity with respect to chlordiazepoxide, diazepam, oxazepam, clorazepate, flurazepam and clonazepam not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Impairment of Judgment Act, as amended, and the date on which this order is published and the date on which it becomes effective.

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9. Other. In all other respects, this order is effective on July 2, 1975.


JOHN R. BARTLETT, Jr., Administrator,
Drug Enforcement Administration.

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Title 26—Internal Revenue
CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY
SUBCHAPTER A—INCOME TAX
[T.D. 7308]

PART 11—TEMPORARY INCOME TAX REGULATIONS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

Notification of Interested Parties Regarding Qualification of Certain Retirement Plans

This document contains temporary income tax regulations under the Employee Retirement Income Security Act of 1974 (29 CFR Part 11) relating to the definition of qualified plans and the requirements that they be given notice of the filing of a request for an advance determination as to the qualified status of a retirement plan.

Under section 3001(a) of the Employee Retirement Income Security Act of 1974 (88 Stat. 892), before the Internal Revenue Service may issue an advance determination whether a pension, profit-sharing or stock bonus plan, a trust which is a part of such a plan, an annuity plan, or a bond purchase plan described in sections 401(a), 403(a), or 405(a) of the Code is exempt from taxation, the applicant must provide the Internal Revenue Service with satisfactory evidence that such applicant has notified each employee qualifying as an interested party under the regulations prescribed under section 7476(b) of the Code of the application for such determination.

Under section 7476(b)(2) of the Code, if the petitioner for a declaratory judgment concerning the qualified status of certain retirement plans was the applicant for such determination, it is the responsibility of the Internal Revenue Service of such status, the Tax Court may hold the filing of a pleading for such declaratory judgment to be premature unless the petitioner establishes to the satisfaction of the Tax Court that such petitioner has notified all interested parties of such application for an advance determination.

In general, the temporary regulations provide rules for determining which employees are interested parties, and rules for giving notice to them.

Adoption of amendments to the regulations. Based on the foregoing, the Temporary Income Tax Regulations under the Employee Retirement Income Security Act of 1974 (26 CFR Part 11) are amended as follows:

There is inserted immediately before the end of Part 11 the following sections:

§ 11.7476-1 Interested parties.

(A) In general. Before the Internal Revenue Service may issue certain advance determinations as to the qualified status of certain retirement plans, the applicant must provide the Internal Revenue Service with satisfactory evidence that such applicant has notified each employee who qualifies as an interested party under regulations prescribed under section 7476(b)(1) of the Code of the application for such determination. See section 3001(a) of the Employee Retirement Income Security Act of 1974 (88 Stat. 905). For the rules for giving notice to interested parties, see § 11.7476-2. Section 7476 provides a procedure for obtaining a declaratory judgment by the Tax Court with respect to the initial or continuing qualification under subchapter D of Chapter 1 of the Code of a retirement plan defined in section 7476(c) in the case of an actual controversy involving:

(1) A determination by the Internal Revenue Service with respect to the initial qualification or continuing qualification under such subchapter of such a plan, or

(2) A failure by the Internal Revenue Service to make a determination with respect to—

(I) Such initial qualification of such a plan, or

(ii) Such continuing qualification of such a plan, if the controversy arises from a plan amendment or plan termination.

Under section 7476(d) the term "retirement plan" means a pension, profit-sharing, or stock bonus plan described in section 401(a), or a trust which is a part of such a plan, an annuity plan described in section 403(a), or a bond purchase plan described in section 405(a). This procedure is available only to the employer, the plan administrator as defined in section 414(g), an employee who qualifies as an interested party as defined in this section, or the Pension Benefit Guaranty Corporation, where such person has an actual controversy involving a determination described in paragraph (a)(1) of this section, failure to make a determination described in paragraph (a)(2) of this section. In the case of an application for such a determination, this procedure is available only if such determination or failure to make such determination is with respect to an application described in paragraph (a)(1) of this section. In the case of an application described in paragraph (b)(5) of this section, if a petitioner was the applicant for the determination, the Tax Court may hold, under section 7476(b), the filing of a pleading for a declaratory judgment to be premature unless the petitioner establishes to the satisfaction of the Tax Court that such petitioner has caused all interested parties to be notified in accordance with this section and § 11.7476-2.

(b) Interested parties. Subject to the provisions of paragraph (b)(5) of this section—

(1) Initial determination and certain first applications. In the case of an application for an advance determination with respect to:

(I) The initial qualification of a plan, or

(II) Whether a plan amendment (other than an amendment described in paragraph (b)(3) of this section) affects the continuing qualification of a plan, if the application is the first application made to the Internal Revenue Service for a determination for a plan year to which section 410 applies to such plan, and all present employees of the employer shall qualify as interested parties.

(2) Plan amendments. In the case of an application (other than an application referred to in paragraph (b)(1) or (b)(3) of this section) for an advance determination as to whether a plan amendment affects the continuing qualification of a plan, the following persons shall qualify as interested parties:

(I) All present employees of the employer eligible to participate under the plan,

(II) If the plan amendment affects participation under the plan, all present employees of the employer, and

(III) If the plan amendment affects the contributions for, or benefits to any former employee, all former employees who have a nonforfeitable right to an accrued benefit under the plan.

For the purpose of paragraph (b)(2)(II) of this section, if qualification of the plan is dependent upon benefits under the plan integrating with those benefits provided under the Social Security Act or a similar program, and if such operation results in excluding any employee or could possibly result in any participant's benefit being reduced to zero and the amendment affects the amount of benefits payable under the plan, then the amendment shall be considered to affect participation under the plan.

(3) Plan terminations. In the case of an application for an advance determination with respect to whether a plan termination affects the continuing qualification of such plan, all present and former employees covered under the plan and any beneficiaries of deceased former employees currently receiving benefits or entitled to receive future benefits under the plan, shall qualify as interested parties.

(4) Exceptions. Notwithstanding any other provision in this section—

(I) Employees who are not eligible to participate under the plan shall not be interested parties—

(A) In the case of a plan described in section 410(a) (relating to collectively bargained plans) which does not cover any employee who is an officer or shareholder or whose total annual rate of compensation ranks such employee among the one-third most highly compensated employees of the employer (but this standard shall not be used for purposes of determining which employees are highly compensated for purposes of subchapter D of Chapter 1 of the Code and the regulations thereunder); or

(B) In the case of a plan which does not exclude employees by virtue of age or length of service, and which clearly meets the eligibility standards of section 410(b)(1)(A).