

public comment period for a technical/agency draft recovery plan: the second revision of the Florida manatee (*Trichechus manatus latirostris*) Recovery Plan.

The Service solicits additional review and comment from the public on this plan. During the previous comment period (December 27, 1994–February 27, 1995), there was some concern expressed that certain individuals and/or groups were not adequately informed of the availability of the draft for public review.

**DATES:** Comments on the draft recovery plan revision must be received on or before June 5, 1995 to receive consideration by the Service.

**ADDRESSES:** Persons wishing to review the draft recovery plan may obtain a copy by contacting the Supervisor, Jacksonville Field Office, U.S. Fish and Wildlife Service, 6620 South Point Dr., South, Suite 310, Jacksonville, Florida 32216 (Telephone: 904–232–2580). Written comments and materials regarding the plan should be addressed to David J. Wesley, Field Supervisor, at the above Jacksonville, Florida address. Comments and materials received are available upon request for public inspection, by appointment, and during normal business hours at the above Jacksonville, Florida address.

**FOR FURTHER INFORMATION CONTACT:** Robert O. Turner, Manatee Coordinator, at the Jacksonville, Florida, address (Telephone: 904–232–2580).

**SUPPLEMENTARY INFORMATION:**

**Background**

Restoring endangered or threatened animals and plants to the point where they are again secure self-sustaining members of their ecosystems is a primary goal of the Service's endangered species program. To help guide the recovery effort the Service is working to prepare recovery plans for most of the listed species native to the United States. Recovery Plans describe actions necessary for the conservation of the species, establish criteria for the recovery levels for downlisting or delisting them, and estimate time and cost for implementing the recovery measures needed.

The Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 *et seq.*) requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act, as amended in 1988, requires that public notice, and an opportunity for public review and comment be provided during recovery plan development. The Service will

consider all information presented during a public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will take these comments into account in the course of implementing approved recovery plans.

The Florida Manatee, a subspecies of the West Indian manatee, was originally listed under the Endangered Species Act on March 11, 1967. The Service developed an initial recovery plan for manatees in 1980. The 1980 plan focused primarily, but not exclusively, on manatees in Florida. In 1986 the Service adopted a separate Recovery Plan for manatees in Puerto Rico. To reflect new information and planning needs for manatees in Florida, the Service revised the original plan in 1989 focusing exclusively on Florida's manatees. The revised plan covered a five-year planning period ending in Fiscal Year 1994. In view of progress since 1989 and planning needs beyond 1994, the Service is once again updating and revising the plan.

**Public Comments Solicited**

The Service solicits written comments on the revised recovery plan described. All comments received by the date specified will be considered prior to the approval of the plan.

**Authority:** The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: March 27, 1995.

**David J. Wesley,**  
Field Supervisor.

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**Bureau of Reclamation**

**Central Valley Project Improvement Act, Criteria for Evaluating Water Conservation Plans**

**AGENCY:** Bureau of Reclamation, Interior.

**ACTION:** Notice of draft decision of evaluation of water conservation plans.

**SUMMARY:** To meet the requirements of the Central Valley Project Improvement Act (CVPIA), the Bureau of Reclamation (Reclamation) developed and published the Criteria for Evaluating Water Conservation Plans (Criteria) dated April 30, 1993. Using this Criteria, Reclamation evaluated the adequacy of all water conservation plans developed by project contractors, including those required by the Reclamation Reform Act of 1982. The Criteria was developed and the plans evaluated for the purpose of promoting the most efficient water use

reasonably achievable by Central Valley Project (CVP) contractors. Reclamation made a commitment (stated within the Criteria) to publish a notice of its draft determination on the adequacy of each CVP contractor's water conservation plan in the **Federal Register** and to allow the public a minimum of 30 days to comment on its preliminary determinations. This program is on-going; an updated list will be published to recognize districts as plans are revised to meet the Criteria.

**DATES:** All public comments must be received by Reclamation by May 5, 1995.

**ADDRESSES:** Please mail comments to the address provided below.

**FOR FURTHER INFORMATION CONTACT:** Betsy Reifsnider, Bureau of Reclamation, 2800 Cottage Way, MP–402, Sacramento, CA 95825. To be placed on a mailing list for any subsequent information, please write Betsy Reifsnider or telephone at (916) 979–2397.

**SUPPLEMENTARY INFORMATION:** Under provisions of Section 3405(e) of the CVPIA (Title 34 of Public Law 102–575), “The Secretary [of the Interior] shall establish and administer an office on Central Valley Project water conservation best management practices that shall \* \* \* develop criteria for evaluating the adequacy of all water conservation plans developed by project contractors, including those plans required by section 210 of the Reclamation Reform Act of 1982.” Also, according to Section 3405(e)(1), these criteria will be developed “\* \* \* with the purpose of promoting the highest level of water use efficiency reasonably achievable by project contractors using best available cost-effective technology and best management practices.”

The Criteria states that all parties (districts) that contract with Reclamation for water supplies (municipal and industrial contracts greater than 2,000 acre feet and agricultural contracts over 2,000 irrigable acres) will prepare water conservation plans which will be evaluated by Reclamation based on the following required information:

1. Coordinate with other agencies and the public
2. Describe the district
3. Inventory water resources
4. Review the past water conservation plan and activities
5. Identify best management practices to be implemented
6. Develop schedules, budgets and projected results
7. Review, evaluate, and adopt the water conservation plan

8. Implement, monitor and update the water conservation plan

The CVP contractors listed below have developed water conservation plans which Reclamation has evaluated and preliminarily determined meet the requirements of the Criteria.

- Arvin Edison Water Shortage District.
- Bella Vista Water District.
- Colusa County Water District.
- Corning Water District.
- Dunnigan Water District.
- Gravelly-Food Water District.
- Monterey County Water Resources Agency.

- Proberta Water District.
- San Juan Water District.
- Santa Barbara, City of.
- Santa Barbara, County of.
- Tea Pot Dome Water District.
- The West Side Irrigation District.
- Thomes Creek Water District.
- Westside Water District.

Public comment on Reclamation's preliminary (i.e., draft) determinations at this time is invited. Copies of the plans listed above will be available for review at Reclamation's Mid Pacific (MP) Region Office and MP's area offices. If you wish to review a copy of the plans, please contact Ms. Reifsnider to find the office nearest you.

Dated: March 28, 1995.

**Franklin E. Dimick,**

*Assistant Regional Director.*

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## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-349]

### Certain Diltiazem Hydrochloride and Diltiazem Preparations; Notice of Commission Decision to Review Portions of an Initial Determination

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review certain portions of the initial determination (ID) and Order No. 52 issued by the presiding administrative law judge (ALJ) on February 2, 1995, in the above-captioned investigation.

**FOR FURTHER INFORMATION CONTACT:** Cynthia P. Johnson, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202-205-3098.

**SUPPLEMENTARY INFORMATION:** On February 1, 1995, the presiding ALJ

issued his final ID finding that there was no violation of section 337. He found that claim 1 of U.S. Letters Patent 4,438,035 ('035 patent) was not infringed by any of respondents' processes, that claim 1 was invalid as obvious under 35 U.S.C. 103, and that the '035 patent was unenforceable because of complainants' inequitable conduct during reexamination proceedings before the U.S. Patent and Trademark Office. In a separate order (Order No. 52), issued on the same date, the ALJ granted respondents' motion for evidentiary sanctions. In that order, he stated that because there is a Commission preference for decisions on the merits based on all the evidence adduced, and because he believes that the same conclusions of law regarding infringement would be appropriate whether or not the sanctions of Order No. 52 are applied, he was imposing sanctions on complainants only as alternate relief, i.e., only if the Commission determines based on all the evidence of record that respondents have infringed claim 1 of the '035 patent.

On February 21, 1995, complainants filed a petition for review of the ALJ's final ID. They also filed a separate petition for review of Order No. 52. On the same day, the Commission investigative attorneys (IAs) filed a petition for review of the ALJ's finding that a domestic industry exists.

On March 6, 1995, the IAs, the Fermion respondents, and the Profarmaco respondents filed oppositions to complainants' petition for review. Respondent Gyma Laboratories also filed an opposition to petition for review indicating that it principally relies on and concurs in the response filed by the Profarmaco respondents.

Having examined the record in this investigation, including the ID and Order No. 52, the Commission has determined to review the issues of (1) claim interpretation, (2) whether claim 1 of the '035 patent is infringed by respondents' processes; (3) whether claim 1 of the '035 patent is invalid as obvious under 35 U.S.C. § 103; (4) whether the '035 patent is unenforceable; and (5) Order No. 52. The Commission has determined not to review the remainder of the ID. The Commission regards the ID as including Order No. 52. The Commission has also denied complainants' motion for leave to file the affidavit of James Gambrell, and denied complainants' request for an oral hearing. With regard to the Gambrell affidavit, the Commission believes that reopening the record to accept the affidavit at this late stage of

the investigation would not be appropriate.

On review, the Commission is particularly interested in answers to the following questions:

(1) Is claim 1 of the '035 patent entitled to any range of equivalents? If not, why not? If so, does the range of equivalents cover (1) use of methyl ethyl ketone, the next higher homolog of acetone, as a solvent when used with potassium hydroxide as a base, or (2) use of potassium carbonate and toluene as the base-solvent combination? Why?

(2) What is the status of the Abic group of respondents? Have they settled their differences with complainants? If so, will a motion to terminate the Abic group of respondents from the investigation be forthcoming?

(3) Is there any suggestion or motivation in the prior art references as a whole applied in the ID to combine those references so as to render obvious under 35 U.S.C. 103 the invention claimed in claim 1 of the '035 patent?

(4) Was there a sale in the United States of the product produced by the Tanabe trade secret KOH/DMSO process within the meaning of 35 U.S.C. 102(b)? Is there applicable case law relevant to complainants' contention that sales of a product for the sole purpose of FDA approval do not constitute an "on sale" bar within the meaning of 35 U.S.C. 102(b)? The Commission is interested in an analysis, based on the evidence of record, of whether sales made solely for purposes of FDA approval constitute an "on sale" bar, taking into account the analysis set forth by the Federal Circuit in considering whether a prior use or sale is a statutory bar in, e.g., *Pennwalt Corp. v. Akzona Inc.* (and cases cited therein) 740 F.2d 1573 (Fed. Cir. 1984). The Commission is also interested in any evidence of record relevant to complainants' contention that the only sales in the United States of Tanabe's trade secret KOH/DMSO process were for purposes of FDA approval. If the Tanabe KOH/DMSO process is found to be prior art, what suggestion or motivation, if any, is there in the prior art that the use of DMSO as a solvent would have rendered the solvents of claim 1 of the '035 patent obvious under 35 U.S.C. 103? Finally, assuming that the Tanabe KOH/DMSO process is prior art, was it more pertinent than the references before the examiner during the reexamination proceedings?

In connection with final disposition of this investigation, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in respondents being required to