

was authorized is found in the previous documents referenced above. The data inputs and methods of estimating take are identical to those used in the initial IHA. NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts or take estimate under the initial IHA.

We refer to the documents related to the initial IHA, which include the **Federal Register** notice of the issuance of the initial Year 1 and Year 2 IHAs for the USACE's construction work (85 FR 1140; January 9, 2020), the USACE's application, the **Federal Register** notice of the proposed IHAs (84 FR 56781; October 23, 2019), and all associated references and documents.

Determinations

The USACE will conduct activities as analyzed in the initial IHA. As described above, the number of authorized takes of the same species and stocks of marine mammals are identical to the numbers that were found to meet the negligible impact and small numbers standards and authorized under the initial IHA and no new information has emerged that would change those findings. The re-issued Year 1 IHA includes identical required mitigation, monitoring, and reporting measures as the initial IHA, and there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; and (4) the USACE's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must review our proposed action with respect to environmental consequences on the human environment.

Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. This action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

However, no incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Authorization

NMFS has issued an IHA to the USACE for in-water construction activities associated with the specified activity from September 1, 2021 through August 31, 2022. All previously described mitigation, monitoring, and reporting requirements from the initial Year 1 IHA are incorporated.

Dated: May 5, 2021.

Catherine Marzin,

*Acting Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2021-09867 Filed 5-7-21; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2021-0027]

Grant of Interim Extension of the Term of U.S. Patent No. 9,364,354; Reducer®

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension for a one-year interim extension of the term of U.S. Patent No. 9,364,354.

FOR FURTHER INFORMATION CONTACT: Ali Salimi by telephone at (571) 272-0909; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to his attention at (571) 273-0909; or by email to ali.salimi@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On April 20, 2021, Neovasc Medical Ltd., the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for a second interim extension of the term of U.S. Patent No. 9,364,354. The patent claims the catheter implantable device, Reducer®. The application for patent term extension indicates that a Premarket Approval Application (PMA) P190035 was submitted to the Food and Drug Administration (FDA) on December 31, 2019.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the once-extended expiration date of the patent, June 6, 2021, a second interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A second interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 9,364,354 is granted for a period of one year from the once-extended expiration date of the patent.

Robert Bahr,

Deputy Commissioner for Patents, United States Patent and Trademark Office.

[FR Doc. 2021-09846 Filed 5-7-21; 8:45 am]

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